

GUIDANCE NOTE NO. 11/2019

Guidance Note on Food for Special Dietary Use for Sportsperson (FSDU for Sportsperson)



Contents

Executive Summary

- 1. Introduction
- 2. Definitions
- 3. Current Regulatory Framework and Status
 - a. Food Safety and Standards Act, 2006, and Regulations.
 - b. National Anti Doping Agency (NADA) Anti Doping Rules, 2015.
- 4. Guidance for Stakeholders
 - a. Sports Fraternity
 - b. Manufacturers
 - c. Importers
 - d. Retailers
 - e. General Public

Appendices:

- I. Frequently Asked Questions
- II. List of Prohibited Substances- World Anti doping Agency (WADA)
- III. Nutrient Requirements and Recommended Dietary Allowances for Indians, Indian Council of Medical research (2010)
- IV. Dietary Guidelines for Indians- A Manual. National Institute of Nutrition (2011)
- V. Recognized Sports in India
- VI. IOC- Consensus Statement: Dietary Supplements and the High-Performance Athlete

Executive Summary

Foods for Special Dietary Uses (FSDU) in general are used by various groups of people. However, use of FSDU by competing sportspersons of different age groups is gaining importance nowadays. Food for Special Dietary Uses for sportspersons are products used to enhance athletic performance, recovery and maintenance of normal health. They may include energy nutrients, vitamins, minerals, amino acids, herbs, or botanical extract, energy supplements, supplements that aid in recovery (protein, BCAAs) and various other ergogenic aids. FSDU for sportspersons are easily available over-the-counter (OTC), on internet, in shops or in fitness clubs. There have been reports of such foods for sportspersons being laced/ spiked with banned substances which are unknown to consumers, leading to unintentional use of prohibited substances which may also be harmful to health. Therefore, it is important that sports nutritionists, health professionals, coaches and sportspersons are acquainted with the relevant information of FSDU for sportspersons like source, ingredients, dosage etc. in order to take informed decisions while consuming them.

To eradicate the menace of doping, the World Anti-Doping Agency (WADA), a foundation initiated by International Olympic Committee (IOC), is coordinating efforts in the fight against doping.

In the sporting ecosystem, Government of India is also committed to provide dope free environment for all the competing sportspersons. The National Anti-Doping Agency (NADA) ensures the implementation of anti-doping program in the country and Food Safety and Standards Authority of India (FSSAI) is the premier organisation responsible for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. Recognizing the need for ensuring coordination and effective partnerships within the Government agencies in the field of sports nutrition, the two regulatory bodies (FSSAI and NADA) are working together with the objective of ensuring availability of safe and dope-free dietary / nutritional products for sportspersons.

This guidance document aims to generate awareness among stake holders viz. Sports Fraternity (sportspersons, coaches, nutritionists, dieticians, physiotherapists and doctors) and manufacturers (domestic and international), importer, retailer, distributor, online retailer and sellers of sports nutrition products and general public about the rules and regulations to be followed for manufacturing, labelling/packaging, marketing, selection, dosage, authenticity, traceability, date marking and awareness of prohibited substances as per WADA list, in the light of Strict Liability Clause, in respect of these products. For better understanding, the document also includes a number of appendices which includes Frequently Asked Questions (FAQs), prohibited list of substances and methods issued by WADA (revised annually and is effective from January 1st of each year), Nutrient Requirements and Recommended Dietary Allowance (RDA) for Indians, Dietary Guidelines for Indians- A Manual (NIN) and IOC-Consensus Statement: Dietary Supplements and the High Performance Athlete.

1. Introduction:

This Guidance Document on "Food for Special Dietary Use for Sportspersons" is the outcome of a collaborative effort at the national level to promote use of dope-free food supplements and nutritional products for sportspersons and to develop and strengthen cooperation in the fields of Sports Nutrition including nutrition practices that enhance lifelong health and fitness of sportspersons.

Food for Special Dietary Use for Sportspersons (FSDU for Sportspersons) contain ingredients required to achieve specific nutritional and performance goals. However, there have been instances where such food may be laced with prohibited substances resulting in unintentional doping. Therefore, it becomes imperative that the sportspersons must have proper guidance on such food and nutritional products so as to ensure that they make informed choices while purchasing these products.

This guidance document attempts to educate the sports fraternity (sportspersons, sports nutritionists, health professionals and coaches) and general public on various types and forms of supplements available in the market; their selection criteria as per requirement; dosage; labelling and claims provisions; authenticity, traceability and source. In addition, the guidance document also provides for:

- Information on current regulatory framework;
- Guidelines that should be followed by Manufacturers, Importers and Retailers;
- World Anti Doping Agency and its list of Prohibited Substances and Methods (2019);
- National Anti Doping Agency, Anti Doping Rules, Strict Liability Clause and Therapeutic Use Exemption for sportspersons;
- Definitions and Frequently Asked Questions;
- Web Links for Nutrient Requirements and Recommended Dietary Allowances for Indians (2010), Dietary Guidelines for Indians-A Manual (2011), IOC- Consensus Statement: Dietary Supplements and the High-Performance Athlete;
- Recognized Sports in India.

2. <u>Definitions</u>

- **i. Sports:** an activity involving physical exertion and skill in which an individual or team competes against another or others for entertainment;
- **ii. Sportsperson:** means an individual who is involved in various types of sports activities as approved by Sports Authority of India (Ministry of Youth Affairs & Sports);
- iii. **Food for Special Dietary Uses (FSDU) for Sportspersons:** FSDU for Sportsperson is a specifically processed or formulated product that satisfies particular dietary requirements which may exist or arise because of certain sports and related physical activities;
- iv. **Ergogenic aid:** a physical, mechanical, nutritional, psychological or pharmacological substance or treatment that either directly improves physiological variables associated

with exercise performance or removes subjective restraints which may limit physiological capacity;

- v. **Nutritional ergogenic aid:** substance found in the diet that is ingested in an effort to produce improved or enhanced sport, exercise, and physical performance;
- vi. **Nutrient Ingredient:** means a vitamin, mineral, or amino acid as specified in Schedule I and Schedule II of the FSS (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods, and Novel Food) Regulations, 2016;.
- vii.**Prohibited Substance.** Substance/ ingredient /drug prohibited by WADA for use by sportspersons.

3. Current Regulatory Framework and Status:

(a) Food Safety and Standards Act, 2006/ Regulations:

> (i) a product that is labelled as which is not representing a conventional food and where such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other forms and are meant for oral administration (not parenteral);

> (ii) such product does not include a drug as defined in clause (b)and ayurvedic, sidha and unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made there under;

(iii) does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and rules made there under and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945.

The Food for Special Dietary Use is also covered in the **Food, Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods, and Novel Food) Regulations, 2016** which covers eight categories of foods, namely, Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Speciality Food containing plant or botanicals, Foods containing Probiotics, Foods containing Prebiotics and Novel Foods. Requirements for such

foods as detailed in these regulations pertain to essential composition; claims and labelling provisions. These standards also include the essential composition, requirements related to claims, labelling, permitted use of additives and the permissible limits of contaminants, toxins and residues. The regulations do not allow the use of hormones or steroids or psychotropic ingredients in any of the articles of food. Furthermore, these regulations provide various Schedules dealing with use of vitamins and minerals, amino acids, ingredients of plants or botanical origin, nutraceuticals, probiotics and prebiotics in these products. The sub category under FSDU shall cover FSDU for Sportspersons considering their special needs.

The Food Safety and Standards Act, 2006 also requires that FBOs (Manufacturers/ Importers / Retailers) comply with the following regulations:

(i) Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011: These regulations stipulate procedure for food license and registration. The Licenses/Registrations are issued to Food Business Operators to commence or carry on any food business as per eligibility criteria for Central License, State License and Registration. A Unique License Number is granted for different kind of business for carrying out food business at a particular premise for which license has been granted. The FBOs are required to buy and sell food products only from, or to, licensed/registered vendors and maintain record thereof

(ii) **Food Safety and Standards (Packaging and Labelling) Regulation, 2011:** These regulations specify general labelling requirements for all pre-packaged foods which includes declaration of list of ingredients, best before date, date of manufacture, date of packaging on packaged food, use by date, expiry date, vegetarian/non-vegetarian food etc. It also provides for some product specific labelling requirements.

(iii) **Food Safety and Standards (Import) Regulation, 2017:** As per Section 25 of the Food Safety and Standard Act, 2006, all imports of articles of food are subject to this Act. It stipulates that no person shall import into India any article of food in contravention of any provision of this Act or any rule and regulation made there under. As provided in the Act, and for the purpose of streamlining the process of clearance of imported food in an efficient and transparent manner, the FSSAI has notified this regulation which lays down the procedure for clearance of food products imported into India and include various provision related to licensing of food importer; clearance of imported food by the Food Authority; food import clearance for specific purposes; storage, inspection and sampling of imported food; laboratory analysis of samples of imported food article and prohibition and privilege for importer to get their concerns, if any, address in respect of the clearance of their food products.

(iv) Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016: An amendment in the FSS (Health Supplements, Nutraceuticals, Food for special Dietary Use, Food for Special medical purpose, Functional food and Novel Food) Regulations, 2016 is currently underway to accommodate standards on sport supplements in the category of Food for Special Dietary Use. This has specify the following requirement –

- Statement and Logo on the label of the food products of FSDU of Sportspersons;
- Declaration on the label related to consumption of product by pregnant, nursing and lactating women or by infants, children under 5 years and elderly;
- Restriction on advertisement of FSDU for sportsperson to general public;
- Prohibit the use of Prohibited substances declared by World Anti-Doping Agency (WADA) in any of the articles of food specified for sport persons.

(b) National Anti Doping Agency: Anti Doping Rules and Regulations:

(i) **Establishment:** Government of India (GOI) is one of the Founder Members of World Anti-Doping Agency (WADA) (1999-2002). GOI has signed the UNESCO Copenhagen Convention on Anti-Doping and accepted the World Anti-Doping Code on 7th March 2008. National Anti-Doping Agency (NADA) of India was established in 2009 and is mandated for Dope free sports in India. New Anti-Doping Rules came into operation w.e.f. 1st January 2015.

(ii) **Objectives:** NADA's primary objectives are to adopt and implement the antidoping rules and policies, which conform to the World Anti-Doping Code, regulate dope control programme by sample collection, result management of adverse analytical findings and imposing sanctions/ ban on athletes'/ athlete support personnel who have violated anti-doping rules and to promote education, research and create awareness about doping and its ill effects.

(iii) **Anti-Doping Rule Violations:** Doping is defined as the occurrence of one or more of the anti-doping rule violations, set forth in Article 2.1 through Article 2.10 of the Anti Doping Rules. The purpose of Article 2 is to specify the circumstances and conduct which constitute anti-doping rule violations. Hearing on doping cases will proceed based on the assertion that one or more of these specific rules have been violated. Athletes and other stakeholders shall be responsible for knowing what constitutes an anti-doping rule violation and the substances and methods, which have been included on the Prohibited List.

(iv) Prohibited Substances and Methods: WADA's determination of the Prohibited Substances and Prohibited Methods that will be included on the Prohibited List, the classification of substances into categories on the Prohibited List, and the classification of a substance as prohibited at all times or in competition only, is final and shall not be subject to challenge by an athlete or other person based on an argument that the substance or method was not a masking agent or did not have the potential to enhance performance, represent a health risk or violate the spirit of sport. The Prohibited List is published on an annual basis for effective implementation from respective calendar year.

(v) Therapeutic Use Exemptions ("TUEs"): The presence of a Prohibited Substance or its Metabolites or Markers, and/or the Use or Attempted Use, Possession or Administration or Attempted Administration of a Prohibited Substance or Prohibited Method shall not be considered an anti-doping rule violation if it is consistent with the provisions of a TUE granted in accordance with the International Standard for TUE.

4. Guidance for Sports Fraternity, Manufacturers, Importers, Retailers & General Public FSDU for Sportsperson may be required to help sportsperson to meet the expenditure of energy during intense muscular effort, to improve exercise performance capacity, improve the efficiency of exercise, enhance recovery from exercise, tolerate intensive training and remain healthy.

FSDU for Sportsperson can be broadly divided into the following categories:

- Carbohydrate-rich energy food products: products high in glycemic carbohydrates essential before, during and after exercise for providing energy and refueling glycogen storage.
- Carbohydrate-electrolyte fluids: Fluids providing carbohydrates as the major energy source and effective in maintaining or restoring hydration status.
- Protein and protein components: high protein and essential amino acids products ensuring endogenous synthesis of proteins, muscle maintenance/gain, and glycogen synthesis when combined with carbohydrates.
- Enriched foods with supplements such caffeine or creatine: some dietary ergogenic aids
- Enriched foods with vitamin and mineral supplements

Specifically the stakeholders may follow the following guidelines to ensure that the FSDU for Sportspersons are genuine products.

A. <u>Sports Fraternity</u>

The sportspersons look to food supplements and nutritional products in addition to their regular diet for deriving many benefits which include promoting adaptation to training, increasing energy supply, enhancing consistent and intensive training by promoting recovery between training sessions, maintaining good health and reducing interruptions to training due to chronic fatigue, illness, or injury, facilitating competitive performance, providing a convenient source of nutrients. Supported for use in sport specific situations using evidence-based protocols some supplements are considered safe, legal and effective in improving sports performance.

Currently, there is no universal system to categorise supplements used by athletes. However, it can be helpful to categorise supplements (or their uses) ¹.

The Ministry of Youth Affairs and Sports has notified following Generic Names of health supplements meant for sportspersons: -

Sr.No.	Name of the Supplement*
1	Multivitamins
2	Whey protein
3	Soya protein
4	Calcium

5	Antioxidant
6	Sports drink including AAs, CHO, Protein and Electrolyte
7	Glucosamine
8	L. Carnitine
9	Creatine Monohydrate
10	Combination of arginine, glutamine, Branched Chain Amino Acids
11	Hematinic
12	Mass Gainers
13	Protein bars

***for further information please refer Appendix VI-** IOC Consensus Statement and the supplements normally used by sportspersons.

The supplements for sportspersons are available in the market in the form of pills, capsules, potions, powders, drinks, bars and gels, which are widely used by sportspersons, however only a few products are supported by evidence based research and some of them may even be harmful to the sportspersons. Hence, it is imperative that the Sports Fraternity i.e. sportspersons, coaches, nutritionists, dieticians and physiotherapists are aware of what is prohibited in as per the WADA list of prohibited substances.

Sportsperson should also carefully examine the risks and benefits of individual supplements before using them and be aware about the misconceptions of 'having higher doses giving better results'. Sportsperson should ensure that supplements be consumed under the guidance of well-informed sports nutritionists, health professionals and coaches. Sportsperson should be aware of dosage, frequency and duration of use of supplements so that the specific sports goals can be achieved.

A Sportsperson ought to choose food first to ensure that their nutritional needs are met. The use of food supplements does not compensate for poor food choices and an inadequate diet. However, to augment diet and to complement additional nutritional needs, the sportsperson may use supplements. In this context, the sportsperson should carefully examine the label of the product for the following: -

- (1) Ingredients List/ Composition
- (2) Date Marking: Expiry/ Best Before Date should be checked before purchasing (both offline and online).
- (3) Package Integrity: It should be ensured that the supplement is properly packed/sealed and there is no evidence of tampering of package.
- (4) Serving Size / Recommended Dosage.
- (5) Authenticity: Sportperson must ensure the authenticity of the supplement before purchasing each individual pack. This can be done through an independent marking which the end user can validate on their own from the manufacturer through Bar Code/QR Code.
- (6) Traceability: Complete visibility of the entire supply chain should be accessed to be aware of the distributor, storage and retailer. It is necessary to confirm the details of the authorised sellers/distributors before purchasing supplements for sportsperson in order to ensure the original source of the product. A complete visibility of the supply chain on retail bills should be available;

(7) Customer Care: for the purpose of making Customer care service details should be available.

B. <u>Manufacturers.</u>

It is important for the FBOs to be aware of the prohibited substances listed by WADA so that these substances are not used as ingredients. The Good Hygienic Practices (GHP), Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Points (HACCP) must be developed and incorporated into the various stages of the production process for supplements.

Manufacturers and Importers must comply with the Food Safety and Standards Act, 2006 and various Regulations thereunder including :-

- (a) <u>Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation,</u> 2011.
- (b) Food Safety and Standards (Packaging and Labelling) Regulation, 2011,
- (c) Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016,
- (d) Food Safety and Standards (Import) Regulation, 2017.

FBOs are required to adopt the following practices: -

- 1. <u>Registration and Licensing of Manufacturer with FSSAI</u>:
 - Manufacturer (Domestic or International) should have an Indian registered office with local contact details for addressing consumer grievances.
 - Manufacturing facility should be periodically audited as per FSSAI Regulations.

2. <u>Labels and Claims</u>: FBOs should ensure that the following declaration are printed on label of the package containing FSDU for Sportspersons: -

- "FOR SPORTSPERSON ONLY"
- Logo (This logo is a part of amendment proposed in the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016 and this will be implemented on the date of publication of said final amendment)



- "Recommended to be used under medical advice or dietetic supervision only"
- " the product is not to be used by pregnant, nursing and lactating women or by infants, children under 5 years and elderly except when medically advised"

- "the food is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet' for the article of food specially prepared for sportsperson;"
- "the food should be used in conjunction with an appropriate physical training or exercise regime."
- "for oral consumption only"

3. <u>Authenticity</u>:

- Manufacturer's product authentication for the consumer (each individual pack should have an independent marking which the end user can validate on their own);
- Manufacturer should ensure that packing is tamper proof/tamper evident;
- Manufacturer should authenticate the seller/distributors and should publish details of authorized seller through their website, advertisements.

4. <u>Traceability</u>:

• Manufacturer should provide complete visibility of the entire supply chain.

5. <u>Date Marking</u>:

• Manufacturer should ensure visibility of Expiry / Best Before Date when selling products through online market places.

The following precautions must be taken before claiming that theFSDU for Sportspersons does not contain any prohibited substance as per WADA": -

1) Periodical tests, preferably bi-annually should be conducted by FBO through FSSAI approved labs;

2) Repository of Certificate of Analysis (COA's) of periodical tests should be maintained by FBO for ready reference;

3) Control samples should be properly preserved and stored as per the FSS Regulations;

C. <u>Importer</u>:

The FBOs/ importers must exercise due diligence and self-regulate while importing FSDU for Sportspersons into the country. Importer must ensure that they import only such products which comply with FSSAI specified standards and regulations. Specifically, the importer should:

- register to obtain license under FSS Act,2006 in respect of the product;
- ensure to keep records of Manufacturer's License while importing goods into India;
- ensure that the imported products are as per FSSAI specified standard by getting the products tested in FSSAI approved labs
- ensure that all relevant documents / information in respect of the entire supply chain of the product being imported are available

- maintain proper records of other relevant information/documents (eg. Date marking, date of import, place of origin, port/place of import into India, storage, inspection and sampling of imported food, reports of laboratory analysis of samples of imported food article, , amenable food labelling provision, etc) are available.
- **D.** <u>**Retailer**</u>: Person involved in retail sale of these products either through online or offline channel should follow or ensure the following:
 - (i) Online.
 - Best before/ Expiry date of the products under this category should be visible when offered for sale through online channel;
 - An online marketplace should be able to provide details as to traceability of the products. This can be ensured through visibility of the supply chain through online invoicing;
 - A dedicated customer support should be provided in respect of any online sales;and
 - Information of the Manufacturer's/Importer's License should be visible when selling products online.

(ii) <u>Offline</u>.

- Requisite License under the FSS Act,2006;
- Traceability of the supply chain. This can be ensured through retail invoicing;
- Maintain Rrecords of the products/inventory for audit ;
- Ensure proper storage conditions

E. <u>General Public</u>:

Consumers must be aware about the difference between general health or food supplements and the food supplements for sportspersons. They must read the label and claims, and must be aware of the prohibited substances as per WADA. In addition to this, consumers should: -

- Choose/select supplements as per their requirements or recommendation by sports nutritionists, health professionals or coaches.
- Confirm the dosage required by them as per their daily activity, gender and age.
- Check Expiry Date/Best Before Date before buying online and offline;
- Look for tamper proof /tamper evident packing;
- Use authentication system provided by Manufacturer;
- In case of grievances/query, customer, contact the manufacturer as per the given customer grievance details.

References:

- Kreider RB, Almada AL, Antonio J, Broeder C, Earnest C, Greenwood M, Incledon T, Kalman DS, Kleiner SM, Leutholtz B, Lowery LM. ISSN exercise & sport nutrition review: research & recommendations. Journal of the International Society of Sports Nutrition. 2004 May 15;1(1):1.
- Bucci, L R Dietary supplements as ergogenic aids. In: Wolinsky I ed. Nutrition in exercise and sport. 1st ed: Boca Raton, New York, CRC Press. 315-323, 1998.
- <u>http://www.fssai.gov.in/home/fss-legislation/food-safety-and-standards-act.html</u>
- <u>www.nadaindia.org</u>
- Supplements & Sports Food Policy, The Irish Sports Council. http://www.gaa.ie/mm/Document/MyGAA/Players/12/22/47/Supplements and Sport Food Policy English.pdf.
- Australian Institute of Sports (AIS), Australian Sports Commission & European Specialist Sports Nutrition Alliance (ESSNA).

<u>FAQs</u>

1. What are Food for Special Dietary Use for sportspersons (FSDU for Sportspersons)?

FSDU for Sportspersons consists of products designed for and used by sportspersons to improve their nutritional status, some aspect of health, wellbeing, performance, muscle growth and/or recovery after training. They are available in various forms like pills, potions, powders, bars and drinks, tablets, capsules and soft gel that promise to give the athlete a winning edge.

2. What is the difference between Health Supplement and FSDU for Ssportspersons?

Health Supplements are dietary substances used to supplement the normal diet of a person (above the age of five years) wherein the quantity of nutrients added shall not exceed the recommended daily allowance.

FSDU for Sportspersons is meant to fulfill the nutrient specific needs of sportspersons where the RDA limits of nutrients may be higher according to the requirements of their physical and training needs.

3. How are FSDU for Sportspersons helpful?

Sportspersons may find these products valuable in helping them achieve their sporting goalsduring pre-event, prolonged session or for post-exercise recovery. Products such as sports drinks maintain the hydration and electrolyte balance during high physical activity. When sportspersons are unable to meet all their nutrient needs from food, a specific nutrient supplement may be prescribed by a sports dietitian or physician to treat or prevent the nutrient deficiency. When used in the right way and right amount at the right time - they can help an athlete train and compete at their best. In many cases they can be shown to directly enhance performance.

4. Are FSDU for Sportspersons Safe to consume?

FSDU for Sportspersons should be consumed under the guidance of well-informed sports fraternity. If these supplements are produced under good manufacturing practices in compliance with FSSAI and NADA/ WADA requirementsand consumed in appropriate dose, FSDU for sportspersons are safe.

But the use of FSDU for sportspersons by sportspersons is a serious concern because in many countries the manufacturing and labeling of supplements do not follow strict rules, which may lead to a supplement containing an undeclared substance that is prohibited under anti-doping regulations. A significant number of positive tests have been attributed to the misuse of food supplements and attributing an Adverse Analytical Finding to a poorly labeled dietary supplement is not an adequate defense in a doping hearing.

The risks of taking FSDU for sportspersons should be weighed against the potential benefit that may be obtained, and athletes must appreciate the negative consequences of an Anti-Doping Rule Violation as a result of taking a contaminated supplement.

Using FSDU for sportspersons that has been subjected to one of the available quality assurance schemes can help to reduce, but not eliminate, the risk of an inadvertent doping infringement.

5. Which are the substances banned for sportspersons.

The Category of prohibited substances and commonly used substances in sports are as under: Anabolic agents (stanozolol, nandrolone, testosterone, methandienone, metenolone, Metenolone, Boldenone, Drostanolone, Norandrosterone, Oxandrolone, Trenbolone, clenbuterol, Androsterone and Etio,); Peptide hormones (Erythropoiesis stimulating agents); Glucocorticosteroids (Prednisolone, betamethasone) and the substances as per the list of prohibited substances by WADA from time to time.

6. What is Strict Liability?

Strict Liability Rule means that each sportspersons is strictly liable for the substances found in his or her bodily specimen, and that an anti-doping rule violation occurs whenever a prohibited substance (or its metabolites or markers) is found in bodily specimen, whether or not the athlete intentionally or unintentionally used a prohibited substance or was negligent or otherwise at fault.

The principle of strict liability is applied in situations where urine/blood samples collected from an athlete have produced adverse analytical results.

7. Do's and Don'ts

<u>Do's:</u>

- Follow a dietary pattern that will support and enhance performance. Choose foods and beverages that you enjoy and that do not bother your stomach. Experiment during the weeks before an event to see which foods work best for you.
- Always remember that there are no quick fixes for improving sports performance.
- Before taking FSDU, assess the need and risks associated with it.
- Be careful and vigilant in using any FSDU. It is difficult to get a guarantee that any particular FSDU is free from prohibited substances.
- FSDU should be taken after seeking advice from a well-informed professional who is acquainted with the list of prohibited substances. Professional advice becomes more necessary because ingredients on the labels of FSDU may be listed differently to how they are shown on the Prohibited List.

• Always keep your FSDU under safe custody.

<u>Don't:</u>

- Do not take FSDU just because a teammate or a competitor is taking it or recommends it.
- Do not exceed the recommended dose. Remember more is not always better. Excessive use of one vitamin or mineral can have a negative impact on the availability or absorption of another.
- Do not take any FSDU manufactured by a company which in the past has been associated with any use of prohibited substances.
- Do not purchase FSDU over internet as the risk of fake supplement products is greatest when buying online.

Appendix II

THE WORLD ANTI-DOPING CODE INTERNATIONAL STANDARD



PROHIBITED LIST

JANUARY 2019



The official text of the *Prohibited List* shall be maintained by *WADA* and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

This List shall come into effect on 1 January 2019

SUBSTANCES & METHODS PROHIBITED AT ALL TIMES

(IN- AND OUT-OF-COMPETITION)

IN ACCORDANCE WITH ARTICLE 4.2.2 OF THE WORLD ANTI-DOPING CODE, ALL PROHIBITED **SUBSTANCES SHALL BE CONSIDERED AS "SPECIFIED SUBSTANCES" EXCEPT SUBSTANCES IN** CLASSES S1, S2, S4.4, S4.5, S6.A, AND PROHIBITED METHODS M1, M2 AND M3.

PROHIBITED SUBSTANCES

SO NON-APPROVED SUBSTANCES

Any pharmacological substance which is not addressed by any of the subsequent sections of the List and with no current approval by any governmental regulatory health authority for human therapeutic use (e.g. drugs under pre-clinical or clinical development or discontinued, designer drugs, substances approved only for veterinary use) is prohibited at all times.

1 ANABOLIC AGENTS

Anabolic agents are prohibited.

1. ANABOLIC ANDROGENIC STEROIDS

(AAS) a. Exogenous* AAS, including:

1-Androstenediol (5^[]-androst-1-ene-3^[],17^[]-diol); 1-Androstenedione (5^[]-androst-1-ene-3,17-dione); 1-Androsterone (30-hydroxy-50-androst-1-ene-17-one); **1-T**estosterone (17^[]-hydroxy-5^[]-androst-1-en-3-one); Bolasterone; Calusterone; Clostebol: Danazol ([1,2]oxazolo[4',5':2,3]pregna-4-en-20-yn-17[-ol); Dehydrochlormethyltestosterone (4-chloro-17^[]-hydroxy-17^[]-methylandrosta-1,4-dien-3-one); Desoxymethyltestosterone (17^[]-methyl-5^[]-androst-2-en-170-ol and 170-methyl-50-androst-3-en-170-ol); Drostanolone: Ethylestrenol (19-norpregna-4-en-17]-ol); Fluoxymesterone; Formebolone: Furazabol (17^[]-methyl [1,2,5]oxadiazolo[3',4':2,3]-50-androstan-170-ol); Gestrinone;

Mestanolone; Mesterolone: Metandienone (17^[]-hydroxy-17^[]-methylandrosta-1,4-dien-3-one); Metenolone: Methandriol; Methasterone (17¹-hydroxy-2¹,17¹-dimethyl-5¹androstan-3-one); Methyldienolone (17^[]-hydroxy-17^[]-methylestra-4,9-dien-3-one): Methyl-1-testosterone (170-hydroxy-170-methyl-50androst-1-en-3-one); Methylnortestosterone (17^[]-hydroxy-17^[]-methylestr-4-en-3-one); Methyltestosterone; Metribolone (methyltrienolone, 17^[]-hydroxy-17^[]methylestra-4,9,11-trien-3-one); Mibolerone: Norboletone: Norclostebol; Norethandrolone: Oxabolone: Oxandrolone: Oxymesterone; Oxymetholone: Prostanozol (170-[(tetrahydropyran-2-yl)oxy]-1'Hpyrazolo[3,4:2,3]-5[-androstane); Quinbolone; Stanozolol; Stenbolone: Tetrahydrogestrinone (17-hydroxy-18a-homo-19-nor-17]pregna-4,9,11-trien-3-one); Trenbolone (17^[]-hydroxyestr-4,9,11-trien-3-one);

and other substances with a similar chemical structure or similar biological effect(s).

b. Endogenous** AAS and their Metabolites and isomers, when administered exogenously, including but not limited to:

4-Androstenediol (androst-4-ene-3.17.17.1.10): 4-Hydroxytestosterone (4,17^[]-dihydroxyandrost-4-en-3-one): 5-Androstenedione (androst-5-ene-3,17-dione); **7**]-hydroxy-DHEA; **7**]-hydroxy-DHEA; 7-keto-DHEA; 19-Norandrostenediol (estr-4-ene-3,17-diol); 19-Norandrostenedione (estr-4-ene-3,17-dione); Androstanolone (5¹/₂-dihydrotestosterone, 17¹/₂-hydroxy-5^[]-androstan-3-one); Androstenediol (androst-5-ene-3, 17, -diol); Androstenedione (androst-4-ene-3,17dione); **Boldenone**; Boldione (androsta-1,4-diene-3,17-dione); Epiandrosterone (31-hydroxy-51-androstan-17-one); Epidihydrotestosterone (17^[]-hydroxy-5^[]-androstan-3one); Epitestosterone; Nandrolone (19-nortestosterone); Prasterone (dehydroepiandrosterone, DHEA, 3¹-hydroxyandrost-5-en-17-one); Testosterone.

2. OTHER ANABOLIC AGENTS

Including, but not limited to: Clenbuterol, selective androgen receptor modulators (SARMs, e.g. andarine, LGD-4033, enobosarm (ostarine) and RAD140), tibolone, zeranol and zilpaterol.

For purposes of this section:

"exogenous" refers to a substance which is not ordinarily produced by the body naturally.

** "endogenous" refers to a substance which is ordinarily produced by the body naturally.

S2 PEPTIDE HORMONES, GROWTH FACTORS, RELATED SUBSTANCES, AND MIMETICS

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited:

- 1. Erythropoietins (EPO) and agents affecting erythropoiesis, including, but not limited to:
 - 1.1 Erythropoietin-Receptor Agonists,
 e.g. Darbepoetins (dEPO);
 Erythropoietins (EPO);
 EPO based constructs [e.g. EPO-Fc, methoxy polyeth-ylene glycol-epoetin beta (CERA)];
 EPO-mimetic agents and their constructs

(e.g. CNTO-530, peginesatide).

1.2 Hypoxia-inducible factor (HIF) activating agents,

- e.g. Argon; Cobalt; Daprodustat (GSK1278863); Molidustat (BAY 85-3934); Roxadustat (FG-4592); Vadadustat (AKB-6548); Xenon.
- **1.3** GATA inhibitors, e.g. K-11706.
- 1.4 TGF-beta (TGF-I) inhibitors, e.g. Luspatercept; Sotatercept.
- 1.5 Innate repair receptor agonists, e.g. Asialo EPO; Carbamylated EPO (CEPO)

- 2. Peptide Hormones and their Releasing Factors,
 - 2.1 Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their releasing factors in males, e.g. Buserelin, deslorelin, gonadorelin, goserelin, leuprorelin, nafarelin and triptorelin;
 - 2.2 Corticotrophins and their releasing factors, e.g. Corticorelin;
 - 2.3 Growth Hormone (GH), its fragments and releasing factors, including, but not limited to: Growth Hormone fragments, e.g. AOD-9604 and hGH 176-191; Growth Hormone Releasing Hormone (GHRH) and its analogues, e.g. CJC-1293, CJC-1295, sermorelin and tesamorelin; Growth Hormone Secretagogues (GHS), e.g. lenomorelin (ghrelin) and its mimetics, e.g. anamorelin, ipamorelin, macimorelin and tabimorelin; GH-Releasing Peptides (GHRPs), e.g. alexamorelin, GHRP-1, GHRP-2 (pralmorelin), GHRP-3, GHRP-4, GHRP-5, GHRP-6, and examorelin (hexarelin).
- 3. Growth Factors and Growth Factor Modulators, including, but not limited to: Fibroblast Growth Factors (FGFs); Hepatocyte Growth Factor (HGF); Insulin-like Growth Factor-1 (IGF-1) and its analogues; Mechano Growth Factors (MGFs); Platelet-Derived Growth Factor (PDGF); Thymosin-II4 and its derivatives e.g. TB-500; Vascular-Endothelial Growth Factor (VEGF);

and other growth factors or growth factor modulators affecting muscle, tendon or ligament protein synthesis/ degradation, vascularisation, energy utilization, regenerative capacity or fibre type switching.

S3 BETA-2 AGONISTS

All selective and non-selective beta-2 agonists, including all optical isomers, are prohibited. Including, but not limited to: Fenoterol; Formoterol: Higenamine; Indacaterol; Olodaterol; Procaterol: Reproterol; Salbutamol; Salmeterol: Terbutaline; Tretoquinol (trimetoquinol); Tulobuterol; Vilanterol.

Except:

- Inhaled salbutamol: maximum 1600 micrograms over 24 hours in divided doses not to exceed 800 micrograms over 12 hours starting from any dose;
- Inhaled formoterol: maximum delivered dose of 54 micrograms over 24 hours;
- Inhaled salmeterol: maximum 200 micrograms over 24 hours.

The presence in urine of salbutamol in excess of 1000 ng/mL or formoterol in excess of 40 ng/mL is not consistent with therapeutic use of the substance and will be considered as an Adverse Analytical Finding (AAF) unless the Athlete proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of a therapeutic dose (by inhalation) up to the maximum dose indicated above.

S4 HORMONE AND METABOLIC MODULATORS

The following hormone and metabolic modulators are prohibited:

- Aromatase inhibitors including, but not limited to:
 2-Androstenol (5^[]-androst-2-en-17-ol);
 2-Androstenone (5^[]-androst-2-en-17-one);
 3-Androstenone (5^[]-androst-3-en-17-ol);
 3-Androstenone (5^[]-androst-3-en-17-one);
 4-Androstene-3,6,17 trione (6-oxo);
 Aminoglutethimide;
 Anastrozole;
 Androsta-1,4,6-triene-3,17-dione

 (androsta-1,4,6-triene-3,5-diene-7,17-dione
 (arimistane); Exemestane;
 Formestane;
 Letrozole;
 - Testolactone.
- Selective estrogen receptor modulators (SERMs) including, but not limited to: Raloxifene; Tamoxifen;

Toremifene.

 Other anti-estrogenic substances including, but not limited to:

Clomifene;

Cyclofenil;

Fulvestrant.

 Agents preventing activin receptor IIB activation including, but not limited, to:

Activin A-neutralizing antibodies; Activin receptor IIB competitors such as:

Decoy activin receptors (e.g. ACE-031); Anti-activin receptor IIB antibodies (e.g. bimagrumab); Myostatin inhibitors such as:

Agents reducing or ablating myostatin expression;

Myostatin-binding proteins (e.g. follistatin, myostatin propeptide);

Myostatin-neutralizing antibodies (e.g.

domagrozumab, landogrozumab, stamulumab).

- 5. Metabolic modulators:
 - 5.1 Activators of the AMP-activated protein kinase (AMPK), e.g. AICAR, SR9009; and Peroxisome Proliferator Activated Receptor [] (PPAR[]) agonists, e.g. 2-(2-methyl-4-((4-methyl-2-(4-(trifluoromethyl) phenyl)thiazol-5-yl)methylthio)phenoxy) acetic acid (GW1516, GW501516);
 - 5.2 Insulins and insulin-mimetics;
 - **5.3** Meldonium;
 - 5.4 Trimetazidine.

S5 DIURETICS AND MASKING AGENTS

The following diuretics and masking agents are prohibited, as are other substances with a similar chemical structure or similar biological effect(s).

Including, but not limited to:

- Desmopressin; probenecid; plasma expanders, e.g. intravenous administration of albumin, dextran, hydroxyethyl starch and mannitol.
- Acetazolamide; amiloride; bumetanide; canrenone; chlortalidone; etacrynic acid; furosemide; indapamide; metolazone; spironolactone; thiazides, e.g. bendroflumethiazide, chlorothiazide and hydrochlorothiazide; triamterene and vaptans, e.g. tolvaptan.
- Except:
- Drospirenone; pamabrom; and ophthalmic use of carbonic anhydrase inhibitors (e.g. dorzolamide, brinzolamide);
- Local administration of felypressin in dental anaesthesia.

The detection in an Athlete's Sample at all times or In-Competition, as applicable, of any quantity of the following substances subject to threshold limits: formoterol, salbutamol, cathine, ephedrine, methylephedrine and pseudoephedrine, in conjunction with a diuretic or masking agent, will be considered as an Adverse Analytical Finding (AAF) unless the Athlete has an approved Therapeutic Use Exemption (TUE) for that substance in addition to the one granted for the diuretic or masking agent.

PROHIBITED METHODS

M1 MANIPULATION OF BLOOD AND BLOOD COMPONENTS

The following are prohibited:

- The Administration or reintroduction of any quantity of autologous, allogenic (homologous) or heterologous blood, or red blood cell products of any origin into the circulatory system.
- Artificially enhancing the uptake, transport or delivery of oxygen.

Including, but not limited to:

Perfluorochemicals; efaproxiral (RSR13) and modified haemoglobin products, e.g. haemoglobin-based blood substitutes and microencapsulated haemoglobin products, excluding supplemental oxygen by inhalation.

 Any form of intravascular manipulation of the blood or blood components by physical or chemical means.

M2 CHEMICAL AND PHYSICAL MANIPULATION

The following are prohibited:

- Tampering, or Attempting to Tamper, to alter the integrity and validity of Samples collected during Doping Control. Including, but not limited to: Urine substitution and/or adulteration, e.g. proteases.
- Intravenous infusions and/or injections of more than a total of 100 mL per 12 hour period except for those legitimately received in the course of hospital treatments, surgical procedures or clinical diagnostic investigations.



The following, with the potential to enhance sport performance, are prohibited:

- The use of polymers of nucleic acids or nucleic acid analogues.
- The use of gene editing agents designed to alter genome sequences and/or the transcriptional, posttranscriptional or epigenetic regulation of gene expression.
- 3. The use of normal or genetically modified cells.

SUBSTANCES & METHODS PROHIBITED IN-COMPETITION

IN ADDITION TO THE CLASSES S0 TO S5 AND M1 TO M3 DEFINED ABOVE, THE FOLLOWING CLASSES ARE PROHIBITED IN-COMPETITION:

PROHIBITED SUBSTANCES

S6 STIMULANTS

All stimulants, including all optical isomers, e.g. d- and l- where relevant, are prohibited.

Stimulants include:

a: Non-Specified Stimulants:

Adrafinil; Amfepramone; Amfetamine; Amfetaminil; Amiphenazole; Benfluorex; Benzylpiperazine; Bromantan; Clobenzorex; Cocaine: Cropropamide; Crotetamide; Fencamine; Fenetylline: Fenfluramine; Fenproporex; Fonturacetam [4-phenylpiracetam (carphedon)]; Furfenorex: Lisdexamfetamine; Mefenorex; Mephentermine; Mesocarb; Metamfetamine(d-); p-methylamfetamine; Modafinil; Norfenfluramine; Phendimetrazine; Phentermine; Prenylamine; Prolintane.

A stimulant not expressly listed in this section is a Specified Substance.

b: Specified Stimulants.

Including, but not limited to:

3-Methylhexan-2-amine (1,2-dimethylpentylamine);4-Methylhexan-2-amine (methylhexaneamine);

4-Methylpentan-2-amine (1,3-dimethylbutylamine); 5-Methylhexan-2-amine (1,4-dimethylpentylamine); Benzfetamine; Cathine**: Cathinone and its analogues, e.g. mephedrone, methedrone, and [] - pyrrolidinovalerophenone; Dimetamfetamine: Ephedrine***; Epinephrine**** (adrenaline); Etamivan; Etilamfetamine: Etilefrine; Famprofazone: Fenbutrazate; Fencamfamin; Heptaminol: Hydroxyamfetamine (parahydroxyamphetamine); Isometheptene; Levmetamfetamine; Meclofenoxate: Methylenedioxymethamphetamine; Methylephedrine***; Methylphenidate; Nikethamide; Norfenefrine: Octopamine; Oxilofrine (methylsynephrine); Pemoline: Pentetrazol: Phenethylamine and its derivatives; Phenmetrazine: Phenpromethamine; Propylhexedrine; Pseudoephedrine****

Selegiline; Sibutramine; Strychnine; Tenamfetamine (methylenedioxyamphetamine); Tuaminoheptane;

and other substances with a similar chemical structure or similar biological effect(s).

Except:

Clonidine;

- Imidazole derivatives for topical/ophthalmic use and those stimulants included in the 2019 Monitoring Program*.
- * Bupropion, caffeine, nicotine, phenylephrine, phenylpropanolamine, pipradrol, and synephrine: These substances are included in the 2019 Monitoring Program, and are not considered Prohibited Substances.
- ** Cathine: Prohibited when its concentration in urine is greater than 5 micrograms per milliliter.
- *** Ephedrine and methylephedrine: Prohibited when the concentration of either in urine is greater than 10 micrograms per milliliter.
- **** Epinephrine (adrenaline): Not prohibited in local administration, e.g. nasal, ophthalmologic, or co-administration with local anaesthetic agents.
- ***** Pseudoephedrine: Prohibited when its concentration in urine is greater than 150 micrograms per milliliter.

S7 NARCOTICS

The following narcotics are prohibited:			
Buprenorphine;			
Dextromoramide;			
Diamorphine (heroin);			
Fentanyl and its derivatives;			
Hydromorphone;			
Methadone;			
Morphine;			
Nicomorphine;			
Oxycodone;			
Oxymorphone;			
Pentazocine;			
Pethidine.			



The following cannabinoids are prohibited:

- Natural cannabinoids, e.g. cannabis, hashish and marijuana,
- Synthetic cannabinoids e.g. ∆9-tetrahydrocannabinol (THC) and other cannabimimetics.

Except:

· Cannabidiol.

S9 GLUCOCORTICOIDS

All glucocorticoids are prohibited when administered by oral, intravenous, intramuscular or rectal routes.

Including but not limited to: Betamethasone; Budesonide; Cortisone; Deflazacort; Dexamethasone; Fluticasone; Hydrocortisone; Methylprednisolone; Prednisolone; Prednisone; Triamcinolone.

SUBSTANCES PROHIBITED IN PARTICULAR SPORTS

P1 BETA-BLOCKERS

Beta-blockers are prohibited In-Competition only, in the following sports, and also prohibited Out-of-Competition where indicated.

- Archery (WA)*
- Automobile (FIA)
- Billiards (all disciplines) (WCBS)
- Darts (WDF)
- Golf (IGF)
- Shooting (ISSF, IPC)*
- Skiing/Snowboarding (FIS) in ski jumping, freestyle aerials/halfpipe and snowboard halfpipe/big air
- Underwater sports (CMAS) in constant-weight apnoea with or without fins, dynamic apnoea with and without fins, free immersion apnoea, Jump Blue apnoea, spearfishing, static apnoea, target shooting, and variable weight apnoea.

*Also prohibited Out-of-Competition

Including, but not limited to:

Acebutolol;	Labetalol;
Alprenolol;	Metipranolol;
Atenolol;	Metoprolol;
Betaxolol;	Nadolol;
Bisoprolol;	Oxprenolol;
Bunolol;	Pindolol;
Carteolol;	Propranolol;
Carvedilol;	Sotalol;
Celiprolol;	Timolol.
Esmolol;	

www.wada-ama.org



Appendix III

Nutrient Requirements and Recommended Dietary Allowances for Indians, Indian Council of Medical research (2010)

http://icmr.nic.in/final/RDA-2010.pdf

Appendix IV

Dietary Guidelines for Indians- A manual. National Institute of Nutrition (2011)

http://ninindia.org/DietaryGuidelinesforNINwebsite.pdf

Appendix V

Recognized Sports in India https://yas.nic.in/sports/support-organisations-1

Appendix VI

IOC- Consensus statement: dietary supplements and the high performance athlete http://bjsm.bmj.com/content/bjsports/early/2018/03/13/bjsports-2018-099027.full.pdf

Maughan RJ, et al. Br J Sports Med 2018;0:1–17. doi:10.1136/bjsports-2018-099027