GUIDANCE DOCUMENT ON THE USE OF SUPPLEMENTS FOR SPORTS PERSONS

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Executive Summary

The primary purpose of guidance document on the use of supplements/ products intended for sports person is an attempt to provide information not only on the use but also about the labeling and claims for the products. The stakeholders are ranging from sports persons to supplement manufacturer, importers, distributors, retailers and general public who will use the information provided in the document.

There have been reports of supplements laced/ spiked with banned substances which are unknown to the consumers and this results in unintentional use of prohibited substances which may also be harmful to health. This document has attempted to provide an overview about the regulatory status and will help the consumers to understand available provisions made in the FSSAI regulations as well as in NADA's Anti-doping rule which implies the Strict Liability Clause for the sportspersons where the use of prohibited substances is strictly prohibited and considered unethical.

To eradicate the menace of doping, the World Anti-Doping Agency (WADA) is a foundation initiated by International Olympic Committee (IOC) which is coordinating the efforts in the fight against doping. In India, it is National Anti-Doping Agency (NADA) which ensures the implementation of anti-doping program in the country.

Supplements are generally used by various groups of people; however, the use by competing sportspersons of different age group is gaining importance nowadays. This guidance document is an outcome of the Memorandum of Understanding (MoU) signed between Food Safety and Standards Authority of India (FSSAI) and NADA in an effort to protect the rights of sportspersons health and to promote fair play.

In the sporting atmosphere, Government of India (GOI) is committed to provide dope free environment for all the competing sports persons. This collaboration enables both the regulatory bodies in bringing hands together to provide healthy ecosystem for sportspersons to make informed choices. In this effort the overview of anti-doping rules/ regulations and FSSAI existing rules/ regulations governing the manufacture, import, distribution and provisions made under the regulations are discussed. The information provided in the document is not only to create awareness to sportspersons but also to manufacturer for a better understanding of the current regulatory processes.

Under the collaboration, FSSAI has already issued a circular to all Food Safety Commissioner for appropriate enforcement and surveillance to ensure the compliance with regard to Food Safety Regulations.

The supplements are available both online and offline mode, covering various types of supplements which are intended for use by sportsperson and also to maintain normal health of public. According to FSSAI regulations, the supplements are being categorized based upon their composition and use, however, there is no specific category of supplements meant for sports person mentioned in the regulation. The Working Group has provided a holistic classification for various supplements/ products intended for use by sports persons and a comprehensive list of supplements used by sports persons and other stakeholders has also been listed out.

The current regulation process for the manufacturer including registration and licensing with FSSAI, label and claims, authenticity, traceability and date marking are briefed in the document. For the better understanding of the document, the appendices list is being provided which includes the definitions, Frequently Asked Questions (FAQs), prohibited list of substances and methods issued by WADA which is revised annually and is effective from January 1st of each year (<u>https://www.wada-ama.org/</u>), Recommended Dietary Allowance (RDA), and Dietary Guidelines has also been provided in the document.

In respect of recognized sports in India, a link of Ministry of Youth Affairs and Sports (MYAS) has been provided - <u>https://yas.nic.in/sports/support-organisations-1</u>

1. Introduction:

This is a guidance document on the use of supplements/ products intended for sportspersons. Supplements marketed as sports nutrition products contain ingredients, which are meant to achieve specific nutritional and performance goals. However, there have been instances where such supplements are laced/spiked with banned substances which are not tested, certified and labelled and, therefore, it becomes imperative that all the stakeholders must educate themselves about various forms of sports supplements, their side effects, authenticity, traceability etc. The purpose of this document is to understand what sport supplements are, selection criteria for using these, their requirements, marketing, labelling/ claim provisions used, knowledge on the prohibited substances which has been listed out by WADA and awareness amongst all the stakeholders with regard to the ingredients used in supplements for sportspersons. Knowledge of Food Safety Regulations should be the cornerstones in keeping a close check on the sport supplements / products. The definitions , frequently asked questions with regard to health supplements, banned substances, current Food laws/ regulations and guidance for the stakeholders, WADA list of prohibited substances, RDA, Dietary Guidelines for Indians and recognized sports in India are covered in this document which is attached at (Appendix I,II, III, IV, V& VI).

The guidance document is meant for Sports Fraternity (Sportspersons, Sports Nutritionists, Health professionals and coaches); Manufacturers- (Domestic and international), Importer, Retailer, Distributer, Online retailer and Sellers in market places and General Public.

2. Memorandum of Understanding (MoU) between Food Safety and Standards Authority of India (FSSAI) and National Anti Doping Agency (NADA) on health supplements and their use in sports nutrition:

To protect the sportsperson's fundamental right to participate in dope-free sport and to promote health, fairness and equality for athletes worldwide, to create good eco-system for competition for the sportsperson and to take informed decisions, FSSAI and NADA the two regulatory bodies collaborated by signing the MoU where in there will be testing of the supplements in FSSAI identified labs, enforcement and surveillance by FSSAI, ensuring that Manufacturers comply with the licensing, labelling and claims as per FSS Regulations.

3. Current Regulatory Framework and Status:

(a) Food Safety and Standards Authority of India (FSSAI) Act/ Regulations:

The Food Safety and Standards Act came into force in 2006 wherein "Food" is defined under section 3(j). As per Subsections b(i), (ii)&(iv) of Section 22 of the Food Safety & Standards Act, 2006, (i) a product that is labelled as a "Food for special dietary uses or functional foods or nutraceuticals or health supplements or similar such foods" 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.

Under the FSS Act, there is **FSS (Licensing & Registration) Regulations, 2011** wherein, every Manufacturer and Importer will have to register or obtain a license from the Food Authority. The food manufacturing unit must comply with Schedule IV – General Hygiene and Sanitary Practices to be followed by Food Business operators of the FSS Act. In case the Manufacturer or Importer fail to comply with the regulations, his license is liable to be suspended.

Another regulation under FSS Act, is **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 includes health supplements, novel foods, foods for special dietary uses (FSDU) and foods for special medical purposes. The sub category under FSDU will cover health supplements for sports persons considering their special needs. The Manufacturer must comply with this regulation to market his products.

The Manufacturers must comply with FSS Regulations on **Labelling**, **Packaging**, **Claims and Advertisement** with regard to labels, claims and packaging of the health supplements.

(b) National Anti Doping Agency (NADA): 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 anti-doping 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.

A. <u>Sports Fraternity</u>.

The sportspersons look to sports foods and supplements in addition to regular diet for many benefits which include promoting adaptations to training, increasing energy supply, allowing more 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.

There is no universal system to categorise supplements used by athletes, but it can be helpful to divide them (or their uses) into products that address specific nutrient deficiencies, sports foods, performance supplements, and supplements for health, adaptation or physique change¹. Supported for use in sport specific situations using evidence-based protocols some supplements are considered safe, legal and effective in improving sports performance. These supplements are classified as follows:

- **1. Sports foods**: Specialised products used to provide a practical source of nutrients when it is impractical to consume everyday foods. Ex: Sports drink, Sports gel, Sports confectionery, Sports bar, Liquid meal, Whey protein, Electrolyte replacement.
- 2. Medical supplements: These are used to treat clinical issues, including diagnosed nutrient deficiencies. It requires individual dispensing and supervision by sports nutritionist / sports physician. Ex: Iron supplement, Calcium supplement, Multivitamin/mineral, Vitamin D, Probiotics.
- **3. Performance supplements:** These are used to directly contribute to optimal performance. They should be used in individualised protocols under the direction of a sports nutritionist / sports physician. While there may be a general evidence base for these products, additional research may often be required to fine-tune protocols for individualised and event-specific use. Ex: Caffeine, B-alanine, Bicarbonate, Beetroot juice, Creatine².

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

*Other additional categories can also be included- Comprehensive table including all categories of food supplements need to be developed.

Sports supplements available in the market in the form of pills, capsules, potions, powders, drinks, bars and gels are widely used by sports persons, but only a few products are supported by evidence based research and some of them may even be harmful to the sportspersons.

Sports person should have awareness of, when, how, how much and how long to use sports supplements so that they can achieve their sports nutrition goals. They should carefully examine the risks and benefits of individual supplements before using them, be aware about the misconceptions of 'having higher doses giving better results' and ensure consumption under guidance of well-informed sports nutritionists, health professionals and coaches. Hence, it is imperative that the Sports Fraternity i.e. sportspersons, coaches, nutritionists, dieticians and physiotherapists should be aware of what is prohibited in and out of competition by looking into the WADA list of prohibited substances.

The use of supplements does not compensate for poor food choices and an inadequate diet. A Sports person ought to choose food first to ensure that their nutritional needs are met. However, to meet the short term nutritional demands of the sports, the sport person may use supplements. In this context, the sports persons 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.
- (4) Serving Size / Recommended Dosage.
- (5) Authenticity: One must ensure authentication before purchasing each individual pack. This can be done through an independent marking which the end user can validate on their own from 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 sports supplement in order to ensure source of the product. A complete visibility of the supply chain on retail bills could be provided;
- (7) Customer Care: In case of any query, customer care should be contacted.

B. <u>Manufacturers.</u>

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

The Manufacturer and Importer must comply with the Food Safety and Standards Act, 2006 and various Regulations enacted under the Act like Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011, Food Safety and Standards (Packaging and Labelling) Regulation, 2011, 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, Food Safety and Standards (Import) Regulation, 2017.

1. <u>Registration& Licensing of Manufacturer with FSSAI (Domestic or International)</u>:

- Manufacturer (Domestic or International)should have an Indian registered office and local contact details for consumer grievances.
- Manufacturing facility should be periodically audited as per FSSAI Regulations.

2. <u>Labels and Claims</u>: Manufacturer should ensure that the following be printed on the Sports Supplement products:-

- (a) Label "Intended for Sports Persons"
- (b) Disclaimer "Not Recommended for infants/children"
- (c) Declaration "Does not contain any Prohibited Substances as per WADA"

3. Authenticity:

- Manufacturer's authentication to the consumer (each individual pack should have an independent marking which the end user can validate on their own from manufacturer);
- Manufacturer should ensure packing to be Tamper Proof/Tamper evident;
- Manufacturer should authenticate the seller/distributors and should publish list of authorized seller details through their website, journals, etc.

4. Traceability:

• Manufacturer should provide access of complete visibility of the entire supply chain (e.g.through bills);

5. Date Marking:

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

Following parameters must be ensured before claiming that the Sports Supplement **"Does not contain any Prohibited Substances as per WADA"**:-

1) Periodical tests to be conducted by Manufacturer (bi-annually) through FSSAI approved labs;

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

3) Declaration from vendors for ingredients going into the formulation as per WADA/NADA to be maintained;

4) Control Samples to be properly maintained and stored as per regulation;

C. <u>Importer</u>:

Since the market in this category is dominated by imported products, it makes it imperative for this market to be regulated. The importers must exercise due diligence and ensure to self-regulate themselves when importing sports supplement into the Country. It is vital that an importer must ensure to import only such products which comply with FSSAI defined standards and regulations. Specifically the importer can ensure the following:

- Should register himself / obtain license in respect of the product;
- Must ensure and keep records that Manufacturer has License as per FSSAI standards when importing goods into India;
- Must ensure that the imported products are as per FSSAI defined standard. This needs to be ensured (by getting the products tested) through testing in FSSAI approved labs as per FSSAI defined limits and records to be maintained;
- Must ensure that he has all the relevant documents / information in respect of the entire supply chain of the product being imported;& while importing products under this category.
- Should readily keep available details in respect of the expiry of the imported product.

D. <u>Retailer</u>:

(i) **Online.** It is imperative that sale of products under this category through online channel should be closely monitored by online marketplace. There is an emergent need to regulate sales of these products through online channels. This can be ensured through the following:

- 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 this category in respect of any online sales;&
- Information of the Manufacturer's License should be visible when selling products online.

(ii) <u>Offline</u>. There is a need to control sales of products under this category through physical retail outlets. Following information should be readily available with the retailer when selling through offline channel:

- Requisite **License** should be available with the retailer;
- Traceability of the supply chain. This can be ensured through **retail invoicing**;

- Readily available records of the products/inventory for inventory audit sold through retail outlets;&
- The products sold under this category through retail outlets should ensure proper storage conditions.

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

Consumers must be aware about the difference between health supplements and sports supplements. They must read the label and claims, if any, and also must be aware of the prohibited substances as per WADA. In addition to this, the following should be ensured by the consumers:-

- 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 should contact the manufacturer as per the given customer grievance details.

Definitions

1. Sports: an activity involving physical exertion and skill in which an individual or team competes against another or others for entertainment.

2. Health Supplements or functional foods or nutraceuticals³: foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist, and may contain one or more of the following ingredients, namely:- (i) plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination; (ii) minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits); (iii) substances from animal origin; (iv) a dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;

3. Sports foods⁴: everyday foods like energy bars, sports drinks and other edible products. Sports foods contain nutrients to meet known daily nutritional needs.

4. Sports supplements⁴: form of pills, capsules, or powders. Supplements contain nutrients and other compounds in supra-physiological amounts.

5. Ergogenic aid⁵: "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.

6. Nutritional ergogenic aids⁶**:** substances found in the diet that are ingested in an effort to produce improved or enhanced sport, exercise, and physical performance.

7. Nutrient Ingredients³: means vitamins, minerals, and amino acids 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.

8. Claim⁷**:** any representation which is printed, oral, audio or visual and states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or otherwise.

Where a claimed benefit is attributed directly to the product or used on labels, advertisements or any other means as a mode of communication to the consumer, it shall be based on statistically significant results from appropriate scientific research study(s), or a well designed, randomized double blind (Unless technically not feasible) clinical study(s), conducted by or under guidance of established research institutions, in line with the principles of GCP (Good Clinical Practices) and Peer Reviewed or published in a Peer reviewed reputed scientific journal with an impact factor of not less than 1 at the time of submission of paper.

9. Health claim^{8:}any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.

10. Prohibited Substances. Substances/ ingredients /drugs prohibited for Sports persons by WADA.

FAQs⁹

1. What are Sports Supplements?

Sports supplement 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 Sports Supplement?

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. Sports supplement is a sub category of health supplement meant only for sports persons where the RDA limits are higher according to their body composition and physical training.

3. How are sports supplements helpful?

Sportspersons may find these products valuable in helping them achieve their day to day nutrition goals. They help in meeting specific goals during 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 - the right amount at the right time on the right occasion - they can help an athlete train and compete at their best. In many cases they can be shown to directly enhance performance.

4. Are Sports Supplements Safe to Take?

Sports supplements should be consumed under the guidance of well-informed sports fraternity. If the quality control is done as per NADA specification, and the target-specific supplement is taken in the appropriate dose, sports supplements are safe.

But the use of dietary supplements 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 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 supplements 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 supplement 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 NADA/ WADA from time to time.

6. What is Strict Liability?

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

It means that each sports persons 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.

7. Do's and Don'ts $^{10\&11}$

<u>Do's:</u>

- Follow a dietary plan that will allow you to adapt your eating and drinking practices to support your performance.
- Due to your high physical activity and increased nutrient needs, you should seek advice from a well-informed professional such as a Dietician / Nutritionist before taking the sports supplements.
- Make sure that the professional is familiar with the WADA/NADA Prohibited List.
- Always remember that there are no quick fixes for improving sports performance.
- Always keep your supplements under safe custody.

<u>Don't:</u>

- Do not take a supplement just because a team mate or a competitor is taking it or recommends it.
- Do not take any supplements made by a company which also manufactures substances which are on the WADA/NADA Prohibited List due to the risk of cross contamination.
- Do not take any supplements that make claims that sound too good to be true. Always validate product claims through non-biased sources.
- Do not take any supplements made by a company which in the past has been associated with positive drugs tests.
- 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.

Appendix III

THE WORLD ANTI-DOPING CODE INTERNATIONAL STANDARD

PROHIBITED LIST JANUARY 2018

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 2018

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

S0. **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.

S1.ANABOLIC AGENTS

Anabolic agents are prohibited.

1. ANABOLIC ANDROGENIC STEROIDS (AAS)

a. Exogenous* AAS, including:

1-Androstenediol (5α -androst-1-ene- 3β ,17 β -diol); 1-Androstenedione (5α-androst-1-ene-3,17-dione); 1-Androsterone (3α -hydroxy- 5α -androst-1-ene-17-one); 1-Testosterone (17 β -hydroxy-5 α -androst-1-en-3-one); 4-Hydroxytestosterone (4,17β-dihydroxyandrost-4-en-3one); Bolandiol (estr-4-ene-3β,17β-diol); **Bolasterone**: Calusterone: Clostebol: Danazol ([1,2]oxazolo[4',5':2,3]pregna-4-en-20-yn-17α-ol); Dehydrochlormethyltestosterone (4-chloro-17 β -hydroxy17 α -methylandrosta-1,4-dien-3-one); Desoxymethyltestosterone (17α -methyl- 5α -androst- 2-en- 17β -ol); Drostanolone; Ethylestrenol (19-norpregna-4-en- 17α -ol); Fluoxymesterone; Formebolone; Furazabol (17α -methyl [1,2,5]oxadiazolo[3',4':2,3]-5 α androstan-17 β -ol); Gestrinone; Mestanolone: Mesterolone: Metandienone (17β -hydroxy- 17α -methylandrosta-1,4-dien3-one); Metenolone: Methandriol: Methasterone (17β -hydroxy- 2α , 17α -dimethyl- 5α androstan-3-one); Methyldienolone (17 β -hydroxy-17 α -methylestra-4,9-dien3-one); Methyl-1-testosterone (17β -hydroxy- 17α -methyl- 5α androst-1-en-3-one); Methylnortestosterone (17β -hydroxy- 17α -methylestr-4-en3-one); Methyltestosterone: Metribolone (methyltrienolone, 17β -hydroxy- 17α methylestra-4,9,11-trien-3-one);

Mibolerone; Norboletone; Norclostebol; Norethandrolone; Oxabolone; Oxandrolone; Oxymesterone; Oxymetholone; Prostanozol (17 β -[(tetrahydropyran-2-yl)oxy]-1'Hpyrazolo[3,4:2,3]-5 α -androstane); Quinbolone; Stanozolo]; Stenbolone; Tetrahydrogestrinone (17-hydroxy-18a-homo-19-nor-17 α pregna-4,9,11-trien-3-one); Trenbolone (17 β -hydroxyestr-4,9,11-trien-3-one); and other substances with a similar chemical structure or similar biological effect(s).

b.Endogenous** AAS when administered exogenously:

19-Norandrostenediol (estr-4-ene-3,17-diol); 19-Norandrostenedione (estr-4-ene-3,17-dione); Androstanolone (5α -dihydrotestosterone, 17β -hydroxy- 5α androstan-3-one); Androstenediol (androst-5-ene- 3β ,17 β -diol); Androstenedione (androst-4-ene-3,17-dione); Boldenone; Boldione (androsta-1,4-diene-3,17-dione); Nandrolone (19-nortestosterone); Prasterone (dehydroepiandrosterone, DHEA, 3β -hydroxyandrost-5-en-17-one); Testosterone; and their metabolites and isomers, including but not limited to:

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3\beta-Hydroxy-5\alpha-androstan-17-one;
5α-Androst-2-ene-17-one:
5\alpha-Androstane-3\alpha, 17\alpha-diol;
5\alpha-Androstane-3\alpha, 17\beta-diol;
5\alpha-Androstane-3\beta,17\alpha-diol;
5\alpha-Androstane-3\beta, 17\beta-diol;
5β-Androstane-3\alpha, 17β-diol;
7α-Hydroxy-DHEA;
7β-Hydroxy-DHEA;
4-Androstenediol (androst-4-ene-3β, 17β-diol);
5-Androstenedione (androst-5-ene-3,17-dione);
7-Keto-DHEA;
19-Norandrosterone;
19-Noretiocholanolone;
Androst-4-ene-3\alpha, 17\alpha-diol;
Androst-4-ene-3\alpha, 17\beta-diol;
Androst-4-ene-3\beta,17\alpha-diol;
Androst-5-ene-3\alpha, 17\alpha-diol;
Androst-5-ene-3\alpha, 17\beta-diol;
Androst-5-ene-3\beta,17\alpha-diol;
Androsterone;
Epi-dihydrotestosterone;
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Epitestosterone; Etiocholanolone.

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.

2. OTHER ANABOLIC AGENTS

Including, but not limited to:

Clenbuterol, selective androgen receptor modulators (SARMs, e.g. andarine, LGD-4033, ostarine and RAD140), tibolone, zeranol and zilpaterol.

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:

- 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 [EPO-Fc, methoxy polyethylene 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; Molidustat; Roxadustat (FG-4592); Xenon.
- 1.3 GATA inhibitors, e.g. K-11706.
- TGF-beta (TGF-β) inhibitors, e.g. Luspatercept; Sotatercept.
- 1.5 Innate repair receptor agonists, e.g. Asialo EPO; Carbamylated EPO (CEPO).
- 2. Peptide Hormones and Hormone Modulators,
 - 2.1 Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their releasing factors,
 - e.g. Buserelin, deslorelin, gonadorelin, goserelin, leuprorelin, nafarelin and triptorelin, in males;
 - 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.
ghrelin and ghrelin mimetics, e.g.
anamorelin, ipamorelin and tabimorelin;
GH-Releasing Peptides (GHRPs), e.g.
alexamorelin, GHRP-1, GHRP-2 (pralmorelin), GHRP-3, GHRP-4, GHRP-5, GHRP-6, and hexarelin.

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-β4 and its derivatives e.g. TB-500; Vascular-Endothelial Growth Factor (VEGF).

Additional 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; Salbutamol; Salmeterol; Terbutaline; 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:

- 1. Aromatase inhibitors including, but not limited to: 4-Androstene-3,6,17 trione (6-oxo); Aminoglutethimide; Anastrozole; Androsta-1,4,6-triene-3,17-dione (androstatrienedione); Androsta-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.
- 4. Agents modifying myostatin function(s) including, but not limited, to: myostatin inhibitors.
- 5. Metabolic modulators:

5.1 Activators of the AMP-activated protein kinase (AMPK), e.g. AICAR, SR9009; and Peroxisome Proliferator Activated Receptor δ (PPAR δ) 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:

1. 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.

2. Artificially enhancing the uptake, transport or delivery of oxygen. Including, but not limited to: Perfluorochemicals; efaproxiral (RSR13) and modified haemoglobin products, e.g. haemoglobinbased blood substitutes and microencapsulated haemoglobin products, excluding supplemental oxygen by inhalation.

3. 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:

1. 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.

2. 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.

M3. GENE DOPING

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

1. The use of polymers of nucleic acids or nucleic acid analogues.

2. The use of gene editing agents designed to alter genome sequences and/or the transcriptional or epigenetic regulation of gene expression.

3. The use of normal or genetically modified cells.

SUBSTANCES & METHODS PROHIBITED IN-COMPETITION

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

PROHIBITED SUBSTANCES

S6STIMULANTS

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-methylamphetamine; 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:

1,3-Dimethylbutylamine; 4-Methylhexan-2-amine (methylhexaneamine); Benzfetamine; Cathine**: Cathinone and its analogues, e.g. mephedrone, methedrone, and α - pyrrolidinovalerophenone; Dimethylamphetamine; 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 2018 Monitoring Program*.

* Bupropion, caffeine, nicotine, phenylephrine, phenylpropanolamine, pipradrol, and synephrine: These substances are included in the 2018 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.

S8. CANNABINOIDS

The following cannabinoids are prohibited:

- Natural cannabinoids, e.g. cannabis, hashish and marijuana,
- Synthetic cannabinoids e.g. Δ9-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; Alprenolol; Atenolol: Betaxolol; Bisoprolol; Bunolol: Carteolol; Carvedilol; Celiprolol; Esmolol; Labetalol: Levobunolol; Metipranolol; Metoprolol; Nadolol; Oxprenolol; Pindolol; Propranolol; Sotalol; Timolol.

www.wada-ama.org

Recommended Dietary Allowances for India

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

Appendix V

Dietary Guidelines for Indians

http://ninindia.org/DietaryGuidelinesforNINwebsite.pdf

Appendix VI

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

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