

Dated, the 9th May 2017

Order

Subject: Use of Performance Enhancing Drugs (PED) in Health supplements.

Under Section 3(j) of the Food of the Food safety & Standards Act, 2006, food has been defined as:

"Food" means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food to the extent defined in clause (zk), genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances.

2. Further as per Subsection (1) (b) (iv) of Section 22 of the Food safety & Standards Act, 2006, Foods for special dietary uses, functional foods, nutraceuticals or health supplements 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.

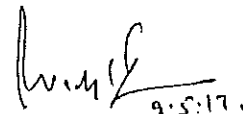
3. Use of health supplements by youth and sportsperson is gaining popularity in India. In view of huge demand of such products, an addition of certain performance enhancing drugs and other banned substances to these otherwise well intended products by unscrupulous manufacturers can not be ruled out. Such substances which are not declared on the labels may risk the health of the unsuspecting consumers. Use of performance enhancer drugs by athletes are also reported in media. India stands third in the world in doping violation cases. A list of such drugs banned by World Anti-Doping Agency (WADA) is attached.

4. It is the responsibility of the food business operators to ensure that any food products do not contain any banned substances.

5. Food Safety Commissioner of States/UTs are requested to initiate special drive to check for use of such substances in food supplements. Strict scrutiny of labels for use of such substance be done. In case of any suspicion, samples may be drawn and sent to the National Anti-Doping Agency (NADA). In such case **Director General, NADA at phone number 011-24368243 may be contacted.** Action as provided under the Food of the Food safety & Standards Act, 2006 shall be initiated against defaulting food business operators.

This issues with the approval of competent Authority.

Encl: As above



S. K. Yadav

Director (Regulatory Compliance)

To

Commissioners of Food Safety of all States/UTs

THE WORLD ANTI-DOPING CODE
INTERNATIONAL
STANDARD



PROHIBITED LIST

JANUARY 2017



WORLD
ANTI-DOPING
AGENCY
play true

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 2017

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 (5 α -androst-1-ene-3 β ,17 β -diol);
1-Androstenedione (5 α -androst-1-ene-3,17-dione);
1-Testosterone (17 β -hydroxy-5 α -androst-1-en-3-one);
4-Hydroxytestosterone (4,17 β -dihydroxyandrost-4-en-3-one);
Bolandiol (estr-4-ene-3 β ,17 β -diol);
Bolasterone;
Calusterone;
Clostebol;
Danazol ([1,2]oxazolo[4',5':2,3]pregna-4-en-20-yn-17 α -ol);
Dehydrochloromethyltestosterone (4-chloro-17 β -hydroxy-17 α -methylandrosta-1,4-dien-3-one);
Desoxymethyltestosterone (17 α -methyl-5 α -androst-2-en-17 β -ol);
Drostanolone;
Ethylestrenol (19-norpregna-4-en-17 α -ol);
Fluoxymesterone;
Formebolone;
Furazabol (17 α -methyl [1,2,5]oxadiazolo[3',4':2,3]-5 α -androstan-17 β -ol);
Gestrinone;

Mestanolone;
Mesterolone;
Metandienone (17 β -hydroxy-17 α -methylandrosta-1,4-dien-3-one);
Metenolone;
Methandriol;
Methasterone (17 β -hydroxy-2 α ,17 α -dimethyl-5 α -androstan-3-one);
Methyldienolone (17 β -hydroxy-17 α -methylestra-4,9-dien-3-one);
Methyl-1-testosterone (17 β -hydroxy-17 α -methyl-5 α -androst-1-en-3-one);
Methylnortestosterone (17 β -hydroxy-17 α -methylestr-4-en-3-one);
Methyltestosterone;
Metribolone (methyltrienolone, 17 β -hydroxy-17 α -methylestra-4,9,11-trien-3-one);
Mibolerone;
Norboletone;
Norclostebol;
Norethandrolone;
Oxabolone;
Oxandrolone;
Oxymesterone;
Oxymetholone;
Prostanozolol (17 β -[[tetrahydropyran-2-yl]oxy]-1'H-pyrazolo[3,4:2,3]-5 α -androstane);
Quinbolone;
Stanozolol;
Stenbolone;
Tetrahydrogestrinone (17-hydroxy-18 α -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);
Androstenediol (androst-5-ene-3 β ,17 β -diol);
Androstenedione (androst-4-ene-3,17-dione);
Boldenone;
Boldione (androsta-1,4-diene-3,17-dione);
Dihydrotestosterone (17 β -hydroxy-5 α -androstan-3-one);
Nandrolone (19-nortestosterone);
Prasterone (dehydroepiandrosterone, DHEA,
3 β -hydroxyandrost-5-en-17-one);
Testosterone;

and their metabolites and isomers, including but not limited to:

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

2. OTHER ANABOLIC AGENTS

Including, but not limited to:

- Clenbuterol;
- Selective androgen receptor modulators (SARMs, e.g. andarine and ostarine);
- Tibolone;
- Zeranol;
- 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.



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. Erythropoietin-Receptor agonists:

- 1.1 Erythropoiesis-Stimulating Agents (ESAs) including e.g.**
Darbepoetin (dEPO);
Erythropoietins (EPO);
EPO-Fc;
EPO-mimetic peptides (EMP), e.g. CNTO 530 and peginesatide;
GATA inhibitors, e.g. K-11706;
Methoxy polyethylene glycol-epoetin beta (CERA);
Transforming Growth Factor- β (TGF- β) inhibitors, e.g. sotatercept, luspatercept;

- 1.2 Non-erythropoietic EPO-Receptor agonists, e.g.**
ARA-290;
Asialo EPO;
Carbamylated EPO.

- 2. Hypoxia-inducible factor (HIF) stabilizers, e.g. cobalt, molidustat and roxadustat (FG-4592); and HIF activators, e.g. argon and xenon.**

3. Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their releasing factors, e.g. buserelin, gonadorelin and leuporelin, in males.

4. Corticotrophins and their releasing factors, e.g. corticorelin.

5. Growth Hormone (GH) and its releasing factors including:

- Growth Hormone Releasing Hormone (GHRH) and its analogues, e.g. CJC-1295, sermorelin and tesamorelin;
- Growth Hormone Secretagogues (GHS), e.g. ghrelin and ghrelin mimetics, e.g. anamorelin and ipamorelin;
- GH-Releasing Peptides (GHRPs), e.g. alexamorelin, GHRP-6, hexarelin, and pralmorelin (GHRP-2).

Additional prohibited growth factors:

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);

Vascular-Endothelial Growth Factor (VEGF) and any other growth factor affecting muscle, tendon or ligament protein synthesis/degradation, vascularisation, energy utilization, regenerative capacity, or fibre type switching.



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;

Vilanterol.

Except:

- Inhaled salbutamol: maximum 1600 micrograms over 24 hours, not to exceed 800 micrograms every 12 hours;
- 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 presumed not to be an intended 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 the use of the therapeutic dose (by inhalation) up to the maximum dose indicated above.



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.
2. Selective estrogen receptor modulators (SERMs) including, but not limited to:
 - Raloxifene;
 - Tamoxifen;
 - Toremifene.
3. Other anti-estrogenic substances including, but not limited to:
 - Clomiphene;
 - 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; and Peroxisome Proliferator Activated Receptor δ (PPAR δ) agonists, e.g. GW 1516;
- 5.2 Insulins and insulin-mimetics;
- 5.3 Meldonium;
- 5.4 Trimetazidine.

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. glycerol and 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

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. haemoglobin-based 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.

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 50 mL per 6 hour period except for those legitimately received in the course of hospital admissions, surgical procedures or clinical investigations.

GENE DOPING

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

1. The transfer of polymers of nucleic acids or nucleic acid analogues.
2. 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



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-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:

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 (parahydroxyamphetaminel);
Isometheptene;
Levmetamfetamine;
Mectofenoxate;
Methylenedioxymethamphetamine;
Methylephedrine***;
Methylphenidate;
Nikethamide;
Norfenefrine;
Octopamine;
Oxilofrine (methytsynephrine);
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 2017 Monitoring Program*.

* Bupropion, caffeine, nicotine, phenylephrine, phenylpropanolamine, pipradrol, and synephrine: These substances are included in the 2017 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.

 **NARCOTICS**


Prohibited:

Buprenorphine;
Dextromoramide;
Diamorphine (heroin);
Fentanyl and its derivatives;
Hydromorphone;
Methadone;
Morphine;
Nicomorphine;
Oxycodone;
Oxymorphone;
Pentazocine;
Pethidine.

 **CANNABINOIDS**

Prohibited:

- Natural, e.g. cannabis, hashish and marijuana, or synthetic Δ^9 -tetrahydrocannabinol (THC).
- Cannabimimetics, e.g. "Spice", JWH-018, JWH-073, HU-210.

 **GLUCOCORTICOIDS**

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

SUBSTANCES PROHIBITED IN PARTICULAR SPORTS

P1 ALCOHOL

Alcohol (ethanol) is prohibited *In-Competition* only, in the following sports. Detection will be conducted by analysis of breath and/or blood. The doping violation threshold is equivalent to a blood alcohol concentration of 0.10 g/L.

- Air Sports (FAI)
- Archery (WA)
- Automobile (FIA)
- Powerboating (UIM)

P2 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;	Levobunolol;
Atenolol;	Metipranolol;
Betaxolol;	Metoprolol;
Bisoprolol;	Nadolol;
Bunolol;	Oxprenolol;
Carteolol;	Pindolol;
Carvedilol;	Propranolol;
Celiprolol;	Sotalol;
Esmolol;	Timolol.

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