Pharmacological aids to Performance: challenges of the prohibited list

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IMIM- Hospital del Mar Medical Research Institute, Barcelona
Chair, IPC Anti-Doping Committee
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1.- Doping: Treating vs Eating

2.- Drugs and more: *The Prohibited List*

3.- Enforcement: Testing
   - Analytical approach
   - TDSSAs

4.- Food: *Supplements*

5.- Regulations: Athlete Support Personnel
1. Doping: Treating vs Eating

- “Anti-doping rules, like competition rules, are sport rules governing the conditions under which sport is played” (World Anti-doping Code 2015).

- What do these AD rules say?: Doping is prohibited!

- What is Doping?
  - **Conceptual Definition**
    “use pharmacological aids to improve performance”: The Prohibited List

Published by WADA every year
Announced every 1st October
Coming into force 1st January
1. Doping: Treating vs Eating

• Structure of the Prohibited List

Substances and Methods Prohibited at all times

S0. Non-Approved Substances  
S1. Anabolic Agents  
S2. Peptide Hormones, Growth Factors, Related Substances and mimetics  
S3. Beta-2 Agonists  
S4. Hormone and Metabolic Modulators  
S5. Diuretics and Masking Agents

M1. Manipulation of Blood and Blood Components  
M2. Chemical and Physical Manipulation  
M3. Gene Doping

Substances Prohibited In Competition

S6. Stimulants  
S7. Narcotics  
S8. Cannabinoids  
S9. Glucocorticoids

Substances Prohibited in Particular Sports

P1. Alcohol  
P2. Beta-Blockers
1. Doping: Treating vs Eating

- What if an Athlete needs treatment with a Prohibited Substance?

Always ask for a Therapeutic Use Exemption (TUE).

Athlete can take medication

- Approved
- Denied

TUE Committee Review

- Sent to ADO

Not Prohibited

Prohibited

PROHIBITED LIST JANUARY 2014
1. Doping: Treating vs Eating

- Why Treating vs Eating?
  ‘We are what we eat ‘(ingest or be exposed to)

- What is the definition of ... food?

- Are ‘nutritional supplements’ drugs or food?

- Does a proper diet covers all nutritional needs of an athlete?

- Is there anything unethical in using nutritional supplements containing substances [drugs?] that cannot be considered food?

Let’s start by ‘TREATING’
2. Drugs and more: *The Prohibited List*

- **Structure of the Prohibited List**

  **Substances and Methods Prohibited at all times**
  
  S0. Non-Approved Substances  
  S1. Anabolic Agents  
  S2. Peptide Hormones, Growth Factors, Related Substances and mimetics  
  S3. Beta-2 Agonists  
  S4. Hormone and Metabolic Modulators  
  S5. Diuretics and Masking Agents

  M1. Manipulation of Blood and Blood Components  
  M2. Chemical and Physical Manipulation  
  M3. Gene Doping

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- S3. Beta-2 Agonists
- S4. Hormone and Metabolic Modulators
- S5. Diuretics and Masking Agents

- **M1. Manipulation of Blood and Blood Components**
- M2. Chemical and Physical Manipulation
- M3. Gene Doping

**Substances Prohibited In Competition**

- S6. Stimulants
- S7. Narcotics
- S8. Cannabinoids
- S9. Glucocorticoids

**Substances Prohibited in Particular Sports**

- P1. Alcohol
- P2. Beta-Blockers
2. Drugs and more: *The Prohibited List*

• Structure of the Prohibited List

**S0. Non-Approved Substances**

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.

“Governmental regulatory health authority? *Stringent Regulatory Authorities* (SRAs)” as defined by the WHO.
2. Drugs and more: *The Prohibited List*

• Structure of the Prohibited List

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P1. Alcohol  
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- Structure of the Prohibited List

**S2. Peptide Hormones, Growth Factors, Related Substances and mimetics**

**S2.1 Erythropoietin-Receptor Agonists**

**S2.1.1 Erythropoiesis-Stimulating Agents (ESAs)**
- EPO and analogues
  - (epoetins, darbepoetin, pegserpoetin, EPO-Fc)
- EPO mimetic peptides (EMPs)
  - (peginesatide, CNTO 530,...)

**S2.1.2 Non-erythropoietic EPO-receptor Agonists**
- (ARA-290, Asialo-EPO, Carbamylated EPO)

**S2.2 Hypoxia-Inducible Factor (HIF) stabilizers**
- (e.g. cobalt, FG-4592)

*Russian athletes admit Xenon doping at Winter Olympics*

Drug has same effect as outlawed EPO which boosts oxygen-carrying blood cells
2. Drugs and more: *The Prohibited List*

- Structure of the Prohibited List

**S2. Peptide Hormones, Growth Factors, Related Substances and mimetics**

**S2.3 Chorionic Gonadotrophin (CG)**
Lutenizing Hormone (LH) and their releasing factors in males
(*buserelin, gonadorelin*).

**S2.4 Corticotrophins**
and their releasing factors (*corticorelin*).
2. Drugs and more: *The Prohibited List*

- Structure of the Prohibited List

### S2. Peptide Hormones, Growth Factors, Related Substances and mimetics

#### S2.5 Growth Hormone (GH) releasing factors and its analogues
(e.g. GHRH, CJC-1295, sermorelin, tesamorelin)

**Growth Hormone secretagogues (GHS)**
Ghrelin and mimetics (anamorelin, ipamorelin)

**GH-releasing peptides (GHRPs)**
(e.g. alexamorelin, GHRP-6, hexamorelin, pralmorelin,...)

**Additional prohibited growth Factors**
FGFs, HGFs, IGF-1, MGFs, PDGF, VEGF and any other growth factor affecting muscle, tendon or ligament.
2. Drugs and more: *The Prohibited List*

- **Structure of the Prohibited List**

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  **Substances Prohibited in Particular Sports**
  
  P1. Alcohol
  P2. Beta-Blockers
2. Drugs and more: *The Prohibited List*

- Structure of the Prohibited List

**S4. Hormones and metabolic modulators**
  
  **S4.1 Aromatase inhibitors**
  
  (6-oxo, aminogluthetimide, androstatrienedione, testolactone, anastrozole, letrozole, exemestane, formestane)

  **S4.2 Selective estrogen receptor modulators (SERMs)**
  
  (raloxifene, tamoxifen, toremifene)

  **S4.3 Other anti-estrogenic substances**
  
  (clomiphene, cyclofenil, fulvestrant)

  **S4.4 Agents modifying myostatin function(s)**
  
  (myostatin inhibitors)
2. Drugs and more: *The Prohibited List*

- Structure of the Prohibited List

**S4. Hormones and metabolic modulators**

**S4.5 Metabolic modulators**

S4.5.1 Activators of AMPK

\( \textit{AICAR} \)

and PPAR\( \delta \) agonists

\( \textit{GW 1516} \)

S4.5.2 Insulins and insulin-mimetics

S4.5.3 Meldonium

S4.5.4 Trimetazidine
3. Enforcement: Testing

- Chemical structure of compounds

<table>
<thead>
<tr>
<th>Compound</th>
<th>Chemical Structure</th>
<th>Molecular Mass (Da)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td><img src="image1" alt="Amphetamine structure" /></td>
<td>135 Da</td>
</tr>
<tr>
<td>Morphine</td>
<td><img src="image2" alt="Morphine structure" /></td>
<td>285 Da</td>
</tr>
<tr>
<td>Δ⁹–THC</td>
<td><img src="image3" alt="Δ⁹–THC structure" /></td>
<td>314 Da</td>
</tr>
<tr>
<td>Testosterone</td>
<td><img src="image4" alt="Testosterone structure" /></td>
<td>288 Da</td>
</tr>
<tr>
<td>Salbutamol</td>
<td><img src="image5" alt="Salbutamol structure" /></td>
<td>239 Da</td>
</tr>
<tr>
<td>Aminogluthetimide</td>
<td><img src="image6" alt="Aminogluthetimide structure" /></td>
<td>232 Da</td>
</tr>
<tr>
<td>Tamoxifene</td>
<td><img src="image7" alt="Tamoxifene structure" /></td>
<td>371 Da</td>
</tr>
</tbody>
</table>
3. Enforcement: Testing

- Chemical structure of compounds

- [Chemical structure images of Furosemide, Probenecid, Betamethasone, Alcohol, and Propranolol]

<table>
<thead>
<tr>
<th>Compound</th>
<th>PM (Da)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furosemide</td>
<td>331</td>
</tr>
<tr>
<td>Probenecid</td>
<td>285</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>393</td>
</tr>
<tr>
<td>Alcohol</td>
<td>46</td>
</tr>
<tr>
<td>Propranolol</td>
<td>259</td>
</tr>
</tbody>
</table>
3. Enforcement: Testing

- Chemical structure of compounds

<table>
<thead>
<tr>
<th>Compound</th>
<th>PM (Da)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythropoietin (EPO)</td>
<td>$\sim 30,500$</td>
</tr>
<tr>
<td>Growth Hormone (hGH)</td>
<td>$\sim 22,000$</td>
</tr>
<tr>
<td>Insuline</td>
<td>5,806</td>
</tr>
</tbody>
</table>
3. Enforcement: Testing

• Analytical Approaches

General purpose methods: GC/MS\textsuperscript{n}, LC/MS\textsuperscript{n}

Volatile compounds (gas chromatography)

Non-volatile compounds (liquid chromatography)
3. Enforcement: Testing

• Analytical Approaches

Singular methods: IEF, SAR-PAGE, Immunoassays, Flow cytometry, etc.
3. Enforcement: Testing

- Analytical Approaches

Singular methods: IEF, SAR-PAGE, IMMUNOASSAYS, etc.

Growth Hormone

22 kDa

$\text{GH}$

anti-$22\text{kDa}\text{-GH}$

20 kDa

$\text{GH}$

anti-$20\text{kDa}\text{-GH}$
3. Enforcement: Testing

- Selection of ‘**additional**’ tests to perform

![Chain of custody form](image)
### 3. Enforcement: Testing

- **WADA’s Technical Document on Sport Specific Analysis (TDSSA)**

<table>
<thead>
<tr>
<th>SPORT</th>
<th>DISCIPLINE</th>
<th>PHYSIOLOGICAL ASSESSMENT</th>
<th>MINIMUM LEVELS OF ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POWER &amp; STRENGTH SPORTS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P&amp;S</td>
<td>ME</td>
<td>CVE</td>
</tr>
<tr>
<td><strong>MUSCULAR ENDURANCE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P&amp;S</td>
<td>ME</td>
<td>CVE</td>
</tr>
<tr>
<td><strong>CV ENDURANCE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P&amp;S</td>
<td>ME</td>
<td>CVE</td>
</tr>
<tr>
<td><strong>Aquatics</strong></td>
<td>Long distance swim (800 m+)</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Open water</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td><strong>Athletics</strong></td>
<td>Long distance (1500 m+)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>Biathlon</strong></td>
<td>Biathlon</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Canoe/Kayak</strong></td>
<td>Dragon boat</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Long distance (1000 m)</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Marathon</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Ocean racing</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>Cycling</strong></td>
<td>Cyclocross</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Mountain bike</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Road</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Track endurance</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td><strong>Modern Pentathlon</strong></td>
<td>Modern pentathlon</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td><strong>Rowing</strong></td>
<td>Rowing</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Skating</strong></td>
<td>Speed/Long (1500 m+)</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Cross country</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Nordic combined</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>Triathlon</strong></td>
<td>Triathlon</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><strong>AIMING SPORTS</strong></td>
<td>P&amp;S</td>
<td>ME</td>
<td>CVE</td>
</tr>
<tr>
<td><strong>PILOT SPORTS</strong></td>
<td>P&amp;S</td>
<td>ME</td>
<td>CVE</td>
</tr>
<tr>
<td><strong>GYMNASTIC SPORTS</strong></td>
<td>P&amp;S</td>
<td>ME</td>
<td>CVE</td>
</tr>
<tr>
<td><strong>BALL AND TEAM SPORTS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P&amp;S</td>
<td>ME</td>
<td>CVE</td>
</tr>
<tr>
<td><strong>COMBAT SPORTS</strong></td>
<td>P&amp;S</td>
<td>ME</td>
<td>CVE</td>
</tr>
</tbody>
</table>
3. Enforcement: Testing

- WADA’s Technical Document on Sport Specific Analysis (TDSSA)

### Appendix 2

#### Minimum Levels of Analysis for Sports and Disciplines for Athletes with Impairments

<table>
<thead>
<tr>
<th>SPORTS</th>
<th>DISCIPLINE</th>
<th>ESA (%)</th>
<th>GH &amp; GHRF (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatics</td>
<td>IPC Swimming (100 m or less)</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Aquatics</td>
<td>IPC Swimming Middle Distance (200-400 m)</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Aquatics</td>
<td>IPC Swimming Long Distance (800 m or greater)</td>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>Archery</td>
<td>Para-Archery</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Athletics</td>
<td>IPC Combined Events</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Athletics</td>
<td>IPC Jumps</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Athletics</td>
<td>IPC Sprint (400 m or less)</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Athletics</td>
<td>IPC Throws</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Athletics</td>
<td>IPC Middle Distance (800-1500 m)</td>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>Athletics</td>
<td>IPC Long Distance (3000 m or greater)</td>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>Badminton</td>
<td>Para-Badminton</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Basketball</td>
<td>Wheelchair Basketball</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Biathlon</td>
<td>IPC Biathlon</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>Bobsleigh</td>
<td>Para-Bobsleigh</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Boccia</td>
<td>Para-Boccia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Canoe/Kayak</td>
<td>Para-Canoe Sprint</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Curling</td>
<td>Wheelchair Curling</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cycling</td>
<td>Para-Cycling Track Sprint</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Cycling</td>
<td>Para-Cycling Road</td>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>Cycling</td>
<td>Para-Cycling Track Endurance</td>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>DanceSport</td>
<td>IPC Wheelchair DanceSport</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Equestrian</td>
<td>Para-Equestrian</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
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- Why Treating vs Eating?
  ‘We are what we eat ‘(ingest or be exposed to)

- What is the definition of ... food?

- Are ‘nutritional supplements’ drugs or food?

- Does a proper diet covers all nutritional needs of an athlete?

- Is there anything unethical in using nutritional supplements containing substances [drugs ?] that cannot be considered food?
4. Food: *Supplements*

- Are nutritional supplements needed?
- Are nutritional supplements performance enhancing?
- Are nutritional supplements safe?

- Caffeine
- Creatine
- Ribose
- Bicarbonate / citrate
- Theophyline
- β-hydroxy-β-methyl-butirate (HMB)
- Glycerol
- Chromium picolinate
- Glutamine
- Carnitine
- Antioxidants
- Proteins and aminoacids
- Colostrum
- Rodhiola Rosea
- Vitamins
- Etc...
Many athletes have produced adverse analytical findings (AAFs) attributed to the use of nutritional supplements.

- **They may be ‘not-properly’ labeled**
  - they may contain substances not mentioned or miss-spelled in the label. (e.g. natural extracts, synonyms, etc.)

- **They may get contaminated during the manufacturing process**
  - residual contaminations may escape the GMP but be detected as doping.

- **They may contain drugs added intentionally**
  - e.g. green tea containing diuretics, protein shakes containing anabolic steroids, etc.
4. Food: *Supplements*


**Cologne List ®**
more safety through tested products

Nutritional supplements and products can contain banned substances.

Cologne List® is a list of nutritional supplements which have been tested for such substances.

By only using products which are on Cologne List® athletes reduce the risk of unintentionally becoming the victims of doping.

Cologne List® is not a recommendation to athletes that they should use a nutritional supplement. Our goal is solely to provide better information and to improve transparency!
4. Food: Supplements

http://www.usada.org

Celebrating USADA's 15th Anniversary

Learn more about the important events that have contributed to USADA's success in protecting the rights of clean athletes for the last 15 years.

Athlete Express
Search Status of Medication
Supplement Information

Report Doping in Sport
Whereabouts Information
Therapeutic Use Exemptions
4. Food: *Supplements*

http://www.usada.org

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Company</th>
<th>What the label says</th>
<th>Prohibited List Classification</th>
<th>Updated</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Andro</td>
<td>IronMagLabs</td>
<td>The Supplement Facts panel lists “1-Androstene 3bol, 17-one”</td>
<td>Anabolic agents</td>
<td>2015-09-27</td>
<td>The product label lists one or more prohibited substances including “1-androstene 3b-ol, 17-one” which is also known as 1-androsterone or 1-DHEA.</td>
</tr>
<tr>
<td>1024</td>
<td>Achievement Through Sciences (ATS) Labs</td>
<td>The Supplement Facts panel lists “7-methoxyflavone.”</td>
<td>Anabolic agents</td>
<td>2015-08-07</td>
<td>Testing of a sample purchased June 2015 revealed the presence of boldione, methasterone, androsta-1,4,6-trienedione, and other prohibited substances.</td>
</tr>
<tr>
<td>17-Diol</td>
<td>Sports One Nutrition</td>
<td>The Supplement Facts panel lists “Epithio-17a-methyltriacontanol” and “Methyl Synephrine”</td>
<td>Anabolic agents</td>
<td>2015-02-12</td>
<td>The product label lists one or more prohibited substances.</td>
</tr>
<tr>
<td>380 Preworkout</td>
<td>Aviva Nutrition</td>
<td>The Supplement Facts panel lists “Amperall (2-amino-4-methylpentane)”</td>
<td>Stimulants</td>
<td>2015-09-10</td>
<td>The product label lists a prohibited substance. The FDA has clarified that DMBA does not meet the definition of a dietary ingredient, and therefore dietary supplements that contain this ingredient are adulterated. To learn more see the FDA Statement on 1,3-Dimethylbutylamine (AMP, Amp Citrate, 4-AMP).</td>
</tr>
<tr>
<td>ABSolute Fuel</td>
<td>BioScience Institute Inc.</td>
<td>The Supplement Facts panel lists “Citrus Aurantium”</td>
<td>Stimulants</td>
<td>2015-09-29</td>
<td>Testing of Lot #13338007 revealed the presence of oxiloxofine (also known as methyloxidone). The</td>
</tr>
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</table>
5. Regulations: Athlete Support Personnel

• What is Doping?
  • **Conceptual Definition**
    “use pharmacological aids to improve performance”: *The Prohibited List*

• **Legal Definition (Art. 1 of The Code):**
  “the occurrence of one or more anti-doping rule violations set forth in Art. 2”

Article 2:
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2.10 prohibited association

2.6.2 Possession by an Athlete Support Person
In-Competition of any Prohibited Substance or any Prohibited Method, or Possession by an Athlete Support Person Out-of-Competition of any Prohibited Substance or any Prohibited Method which is prohibited Out-of-Competition in connection with an Athlete, Competition or training, unless the Athlete Support Person establishes that the Possession is consistent with a TUE granted to an Athlete in accordance with Article 4.4 or other acceptable justification.
What is Doping?

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  2.10 prohibited association

Association by an Athlete or other Person subject to the authority of an Anti-Doping Organization in a professional or sport-related capacity with any Athlete Support Person who:

2.10.1 If subject to the authority of an Anti-Doping Organization, is serving a period of Ineligibility; or
5. Regulations: Athlete Support Personnel

<table>
<thead>
<tr>
<th>Last name</th>
<th>First name</th>
<th>Nationality</th>
<th>Suspension dates</th>
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<td>Life</td>
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</table>
5. Regulations: Athlete Support Personnel

• Consequences of Doping
  • **Sanctions (ineligibility periods)**

"the occurrence of one or more anti-doping rule violations set forth in Art. 2"

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10.3.3 For violations of Article 2.7 or 2.8, the period of Ineligibility shall be a minimum of four years up to lifetime Ineligibility, depending on the seriousness of the violation. An Article 2.7 or Article 2.8 violation involving a Minor shall be considered a particularly serious violation and, if committed by Athlete Support Personnel for violations other than for Specified Substances, shall result in lifetime Ineligibility for Athlete Support Personnel. In addition, significant
5. Regulations

- Consequences of Doping
  - **Sanctions (ineligibility periods)**
    - “the occurrence of one or more anti-doping rule violations set forth in Art. 2”

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10.3.4 For violations of Article 2.9, the period of Ineligibility imposed shall be a minimum of two years, up to four years, depending on the seriousness of the violation.

10.3.5 For violations of Article 2.10, the period of Ineligibility shall be two years, subject to reduction down to a minimum of one year, depending on the Athlete or other Person’s degree of Fault and other circumstances of the case.
Thank you!