



IAAF REGULATIONS GOVERNING ELIGIBILITY OF FEMALES WITH HYPERANDROGENISM TO COMPETE IN WOMEN'S COMPETITION

In force as from 1st May 2011

INTERNATIONAL ASSOCIATION OF ATHLETICS FEDERATIONS

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Preface

Since 1928, competition in Athletics has been strictly divided into male and female classifications and females have competed in Athletics in a separate category designed to recognize their specific physical aptitude and performance.

The difference in athletic performance between males and females is known to be predominantly due to higher levels of androgenic hormones in males resulting in increased strength and muscle development.

It is also known from experience that there are rare cases of young females competing in Athletics today who are affected by hyperandrogenism which, if the condition remains undiagnosed or neglected, can pose a risk to health. Despite the rarity of such cases, their emergence from time to time at the highest level of women's competition in Athletics has proved to be controversial since the individuals concerned often display masculine traits and have an uncommon athletic capacity in relation to their fellow female competitors.

These Regulations set out to formulate a reasonable and suitably adapted approach by the IAAF to the management of such cases in Athletics and are predicated upon the following underlying principles:

- The early prevention of problems associated with hyperandrogenism;
- A respect for confidentiality in the medical process and the need to avoid public exposure of young females with hyperandrogenism who may be psychologically vulnerable;
- The evaluation of complex cases on an anonymous basis through the use of a panel of independent international medical experts in the field;

¹ Hyperandrogenism is a term used to describe the excessive production of androgenic hormones (Testosterone).

- A respect for the very essence of the male and female classifications in Athletics;
- A respect for the fundamental notion of fairness of competition in female Athletics;
- An acknowledgement that females with hyperandrogenism may compete in women's competition in Athletics subject to compliance with IAAF Rules and Regulations.

Chapter 1 Scope of Regulations

- 1.1 These Regulations establish a framework for the determination of the eligibility of females with hyperandrogenism to participate in International Competitions (as defined in IAAF Rules) in the female category.
- 1.2 The Regulations are of mandatory application to all athletes competing, or seeking to compete, in International Competitions and are recommended as a guide to National Federations in Athletics for the management of any cases that might arise at the national level.
- 1.3 No female with hyperandrogenism shall be permitted to compete in the female category of an International Competition until her case has been evaluated by the IAAF in accordance with these Regulations.
- 1.4 These Regulations replace the IAAF's previous Gender Verification Policy and the IAAF has now abandoned all reference to the terminology "gender verification" and "gender policy" in its Rules.

Chapter 2 The initial notification/investigation of cases under the Regulations

- 2.1 Any female athlete with hyperandrogenism who seeks to compete in an International Competition shall be required to notify the IAAF so that her case can be evaluated in accordance with these Regulations. This applies both to athletes with hyperandrogenism who have already been diagnosed and to those who are still in the course of diagnosis. Notification shall be made in strict confidence to the IAAF Medical Manager (a physician), either directly or via her National Federation's team doctor or other supervising physician.

- 2.2 In addition, the IAAF Medical Manager may initiate a confidential investigation of any female athlete if he has reasonable grounds for believing that a case of hyperandrogenism may exist. The IAAF Medical Manager's reasonable grounds for belief in a case may be derived from any reliable source, including:
- 2.2.1 an athlete making an approach to the IAAF or her National Federation for advice or clarification on an associated medical condition, either in person or through her personal doctor or other appointed representative;
 - 2.2.2 the results of a routine pre-participation or other medical examination conducted by an athlete's National Federation;
 - 2.2.3 a report from a Doping Control Officer following a routine doping control procedure;
 - 2.2.4 the analytical results from a routine anti-doping test revealing an atypical steroid profile or abnormal profile within the Athlete's Biological Passport; or
 - 2.2.5 information received by the IAAF Medical Delegate or other responsible medical official at a competition.

Chapter 3 Confidential management of cases

- 3.1 All cases managed under these Regulations shall be treated in strict confidence.
- 3.2 As a necessary pre-condition of her eligibility to compete, the athlete shall consent to the disclosure of her medical information to such person or persons as may be required to review such information in accordance with these Regulations. Medical information for these purposes shall include both information provided at the time of first notification or investigation of an athlete's case and any further information as may be collected in the course of implementation of these Regulations.
- 3.3 The IAAF Medical Manager and members of the IAAF Medical Department involved in the management of an athlete's case under these Regulations shall conduct their activities at all times in strict confidence. All medical information and data relating to an athlete pursuant to these Regulations shall be treated as sensitive personal

information and the IAAF Medical Manager shall ensure at all times that it is processed as such in accordance with applicable data protection and privacy laws.

- 3.4 Should the assistance of external, independent experts be required under these Regulations (for example, from the Expert Medical Panel described below), the athlete's medical data and information shall be circulated by the IAAF Medical Manager on an anonymous basis without identifying the name of the athlete involved.
- 3.5 The IAAF shall only retain an athlete's medical data and information as long as is necessary to keep the athlete's case under review in accordance with IAAF Rules and/or the provisions of these Regulations or where otherwise required by applicable law.
- 3.6 Once the athlete's medical information and data no longer serves any of the above purposes, it shall be destroyed or permanently anonymised.

Chapter 4 The Expert Medical Panel

- 4.1 The IAAF shall appoint a pool of independent medical experts to review cases that are submitted to it under these Regulations, one of whom shall be appointed as the Chairman. Members shall be appointed to the pool for an initial period of 4 years.
- 4.2 The current Chairman and list of independent medical experts appointed by the IAAF are set out in Appendix 1 to these Regulations.
- 4.3 In the course of exercising its functions under these Regulations, the Expert Medical Panel may:
 - (i) exchange views on the athlete's case by e-mail, telephone, facsimile or in person;
 - (ii) call for any evidence or documents that it considers to be relevant to the athlete's case; or
 - (iii) seek any medical, scientific or other specialist advice that it considers necessary in order to review the athlete's case.

Chapter 5 Medical Assessment of cases

5.1 Cases may be investigated under these Regulations according to the following three levels of medical assessment:

(i) Level 1 – Initial Clinical Examination

Level 1 provides for an initial clinical examination of the athlete and the compilation of specific clinical and anamnestic data.

(ii) Level 2 – Preliminary Endocrine Assessment

Level 2 provides for a preliminary endocrine assessment carried out on urine and blood samples (serum) collected from the athlete and analysed in an accredited laboratory.

(iii) Level 3 – Full examination and diagnosis

Level 3 provides for a full examination and whenever possible diagnosis of the athlete carried out at a specialist reference centre approved by the IAAF.

Note: These Regulations merely set out an overall framework for the management of cases that might arise. The specific procedure to be adopted in each case will depend on the nature, timing and/or complexity of the individual case and these Regulations should be read accordingly. For example, depending on the circumstances of the case, the Level 1 and Level 2 examinations may be performed together, alternatively, the athlete may be referred directly to Level 3. If an athlete with hyperandrogenism has already been diagnosed prior to the entry into force of these Regulations, depending on the available data for the athlete, the IAAF Medical Manager may decide that no further medical assessment under these Regulations is required.

Level 1 - Initial Clinical Examination

5.2 The athlete shall normally be required in the first instance to attend an initial clinical examination and compilation of clinical and anamnestic data in her case.

- 5.3 The initial clinical examination shall be conducted in accordance with the Medical Guidelines, a copy of which is attached at Appendix 2 to these Regulations.
- 5.4 Prior to conducting the initial clinical examination, the examining physician shall explain to the athlete the purpose of the examination and the fact that it is part of an overall process to be conducted under IAAF Rules in accordance with the provisions of these Regulations². Where the athlete is a minor, the examining physician shall provide such explanation to the athlete's parents or legal guardian(s).
- 5.5 The athlete (or athlete's parents or legal guardian(s) where the athlete is a minor) shall designate a physician to be the recipient of the results of the initial clinical examination on her behalf.
- 5.6 The results from the initial clinical examination and compilation of clinical and anamnestic data shall be transmitted confidentially to the athlete's designated physician and to the IAAF Medical Manager.

Level 2 - Preliminary Endocrine Assessment

- 5.7 The athlete may also be asked to submit to a preliminary endocrine assessment.
- 5.8 In such event, the athlete shall be required to provide urine and blood (serum) samples for analysis in accordance with the Medical Guidelines in Appendix 2. The samples shall be sent to a laboratory which is accredited for the conduct of such analyses. If no accredited laboratory is available in the athlete's location, the IAAF shall decide upon the accredited laboratory to be used in each case.
- 5.9 In the exceptional event that a preliminary endocrine assessment under Level 2 is conducted before an initial clinical examination (Level 1), the athlete shall be fully advised as to the purpose of the endocrine assessment and the fact that it is part of an overall process to be conducted under IAAF Rules in accordance with the provisions of these Regulations³. Where the athlete is a minor, the physician shall provide such explanation to the athlete's parents or legal guardian(s). The athlete (or athlete's parents or legal guardian(s) where the athlete is a minor) shall

² A summary document of the process involved shall be available for the examining physician's use if need be.

³ A summary document of the process involved shall be available for the examining physician's use if need be.

designate a physician to be recipient of the results of the preliminary endocrine assessment on her behalf.

- 5.10 The laboratory shall analyze the athlete's urine for at least the following androgenic hormones (including their urinary metabolites): Testosterone, Epitestosterone, Androsterone, Etiocholanolone, 5 α -androstanediol, 5 β -androstanediol, Dihydrotestosterone and Dehydroepiandrosterone.
- 5.11 The laboratory shall analyze the athlete's blood (serum) for recorded levels of Testosterone and Sex Hormone-Binding Globulin at a minimum. Depending on the circumstances of the case, the IAAF may also decide to analyse for recorded levels of additional hormones/substances, including, but not limited to, Dihydrotestosterone, Luteinizing Hormone, Follicle-stimulating Hormone, Estradiol, Anti-Mullerian Hormone, Inhibin B, 17-OH-Progesterone, Dehydroepiandrosterone Sulfate and Delta 4 Androstenedione.
- 5.12 The report of the analyzing laboratory in respect of the above analyses shall be transmitted confidentially to the athlete's designated physician and to the IAAF Medical Manager.

Initial Review of results by the IAAF

- 5.13 The IAAF Medical Manager shall conduct an initial review of any results obtained from the medical assessments conducted under Levels 1 and Level 2 of these Regulations in order to decide whether to refer the athlete's case for independent review by an Expert Medical Panel.
- 5.14 Upon review of the results obtained under the Level 1 and Level 2 assessments, the IAAF Medical Manager may arrange for the collection and analysis of a further urine sample from the athlete to ensure that the athlete's results are not the consequence of an exogenous administration of androgens.
- 5.15 In appropriate cases, the IAAF Medical Manager may also arrange for the collection and analysis of further blood and/or urine samples from the athlete in order to confirm the results obtained from the preliminary endocrine assessment under Level 2 and/or as an additional tool for diagnosis.

- 5.16 The IAAF Medical Manager may in deciding to refer an athlete's case to an Expert Medical Panel seek an advisory opinion from such person or persons as he considers appropriate.

Referral of case to an Expert Medical Panel

- 5.17 If the IAAF Medical Manager so decides after his initial review of the athlete's Level 1 and Level 2 results, the case shall be referred to an Expert Medical Panel.
- 5.18 An Expert Medical Panel constituted to review a case under these Regulations shall normally comprise the Chairman and a minimum of two other persons from the pool of experts listed in Appendix 1. In exceptional cases, the Chairman or another appointed person may sit as a single independent expert to review a case.
- 5.19 The composition of the Expert Medical Panel shall be decided upon by the IAAF Medical Manager and, unless otherwise unavailable, the Chairman shall sit in each case. The IAAF Medical Manager may consult with the Chairman as regards the appointment of any member of the Panel from the pool of experts at Appendix 1 depending on the circumstances of the case. No member shall be appointed to the Expert Medical Panel if he or she is involved in any aspect of the medical examination of the athlete.
- 5.20 In each case, the members of the Expert Medical Panel shall sign confidentiality undertakings and shall confirm in writing that they have no conflicts of interest.
- 5.21 The Expert Medical Panel once constituted shall review the athlete's medical information and data forwarded by the IAAF Medical Department and it shall determine either that no further medical assessment of the athlete is required or, if it considers that there are grounds to indicate an athlete with hyperandrogenism, to proceed to a full examination and diagnosis of the athlete under Level 3. To enable it to make such a determination in this regard, the Expert Medical Panel may call for such additional data or information as it considers necessary.
- 5.22 If the Expert Medical Panel determines following its review that a full examination and diagnosis is required under Level 3, the athlete and her designated physician shall be notified as soon as practicable by the IAAF.

- 5.23 At the same time as referring an athlete's case to a full examination under Level 3, if the athlete states an intention to continue competing, the Expert Medical Panel may make a recommendation to the IAAF based on the evidence before it (Level 1 and/or Level 2 results and/or other evidence) as to whether or not the athlete should be declared provisionally eligible to compete in women's competition whilst further assessment of her case is conducted. If the Expert Medical Panel makes such a recommendation, the IAAF Medical Manager shall take a decision on the athlete's provisional eligibility taking account of the recommendation that it has received.
- 5.24 If the IAAF Medical Manager decides that the athlete shall not be eligible to compete whilst undergoing further assessment of her case, he shall notify the decision to the athlete and her designated physician and, where necessary, her National Federation. The IAAF's decision in this regard shall not be subject to review but the athlete shall be entitled to an expedited follow up of her case and a final decision taken as regards her eligibility under these Regulations.
- 5.25 If the IAAF Medical Manager decides that the athlete should be declared provisionally eligible to compete whilst undergoing further assessment of her case, he shall notify the decision to the athlete and her designated physician and, where necessary, her National Federation. At the same time, he shall notify the athlete that, in accordance with IAAF Rules, if it is later decided under the Regulations that she was not eligible to have competed during that period, all of her competition results as from the date of notification of her provisional eligibility shall be annulled (including, where applicable, the results of any team in which she has competed).

Level 3 - Full Examination and Diagnosis

- 5.26 If the Expert Medical Panel so determines, the athlete shall be required to submit to a full examination at an IAAF-approved specialist reference centre so that a final and precise diagnosis of the athlete whenever possible may be carried out. The examination shall take place as soon as possible after notification to the athlete and her designated physician. If the IAAF has taken a decision that the athlete is not provisionally eligible to compete whilst further assessment of her case is conducted, the Level 3 examination shall take place on an expedited basis and the IAAF Medical Manager may impose a deadline for this purpose.

- 5.27 The Level 3 examination shall be conducted at the specialist reference centre listed in Appendix 3 that is located closest geographically to the athlete's habitual place of residence, unless the athlete chooses to be examined in another such reference centre (in which event she will be responsible for any additional costs that might be incurred as a result).
- 5.28 Prior to conducting the Level 3 examination, the examining physician shall explain to the athlete the purpose of the examination, the nature of the testing to be conducted and the potential consequences of such examination both for the athlete's health and for her eligibility in Athletics. The athlete shall provide her informed written consent to the examination in accordance with applicable laws. Where the athlete is a minor, parental or legal guardian consent shall be obtained.
- 5.29 The specialist reference centre shall conduct a full examination on the athlete and shall carry out a diagnosis of the athlete in accordance with best medical practice. In cases of Disorders of Sex Development, the diagnosis shall further be made in accordance with the recommendations for diagnostic evaluation set out in the Consensus Statement on Management of Intersex Disorders at Appendix 4 to these Regulations. The examination at Level 3 shall normally include the following different types of test: physical, laboratory (including genetic testing), imaging and psychological assessment.
- 5.30 At the same time as the Level 3 examination is conducted, the examining physician shall collect an additional urine sample and blood sample and send them for analysis to an accredited laboratory to be specified by the IAAF. The samples shall be sent in conditions that guarantee their integrity and they shall be analysed upon receipt for the hormones/substances listed in paragraph 5.10 (urine) and 5.11 (blood). The results of the analyses shall be transmitted confidentially to the athlete's designated physician and the IAAF Medical Manager.
- 5.31 Following completion of a full examination under Level 3 at the specialist reference centre, the athlete's diagnosis and prescribed medical treatment, together with all results obtained from the examination, shall be transmitted confidentially by the reference centre to the athlete's designated physician and to the IAAF Medical Manager.

Chapter 6 Recommendation of Expert Medical Panel on Athlete's Eligibility

- 6.1 Once the athlete's diagnosis has been carried out, if the athlete states an intention to continue competing in Athletics, the IAAF Medical Department shall forward to the Expert Medical Panel all further results obtained from the examination under Level 3, so that the Expert Medical Panel may conduct a further comprehensive review of the athlete's case and make an informed recommendation on her eligibility to compete in women's competition.
- 6.2 In conducting its further review of the athlete's case, the Expert Medical Panel shall have access to all potentially relevant information, including:
- (i) the results of any initial clinical examination and compilation of clinical and anamnestic data conducted under Level 1, including clinical signs of virilization (physical appearance, deepness of voice, body hair etc), genital characteristics (clitoral hypertrophy) and anamnestic information;
 - (ii) the results of any blood analyses conducted under Level 2, including reported levels of androgenic hormones;
 - (iii) the results of any urine analyses conducted under Level 2, including reported levels of androgenic hormones and their urinary metabolites;
 - (iv) the results of any further urine and/or blood analyses as may have been conducted after Level 2;
 - (v) the results of the full examination conducted under Level 3, including laboratory data (hormonal and genetic tests results); and
 - (vi) any other information the Expert Medical Panel may determine as relevant to assessment of the athlete's case, including any written submission and/or further documents as may be requested from the athlete.
- 6.3 Upon review of the athlete's information, the Chairman of the Expert Medical Panel may seek any further expert opinion(s) in relation to the athlete's case as he considers to be necessary. Any such third party communications shall be on an anonymous basis without identifying the name of the athlete involved.

- 6.4 Following its final review of the athlete's case, the Expert Medical Panel shall be asked to make a recommendation as regards the athlete's eligibility to compete in women's competition based on her reported androgen levels and taking into consideration any androgen resistance that she might have.
- 6.5 The Expert Medical Panel shall recommend that the athlete is eligible to compete in women's competition if:
- (i) she has androgen levels below the normal male range; or
 - (ii) she has androgen levels within the normal male range but has an androgen resistance such that she derives no competitive advantage from having androgen levels in the normal male range.

Androgen levels for the purposes of paragraph 6.5 are measured by the levels of Total Testosterone in serum.

Normal male range Total Testosterone Levels - ≥ 10 nmol/L

- 6.6 The burden of proof shall be on the athlete to establish, where applicable, that she has an androgen resistance such that she derives no competitive advantage from androgen levels in the normal male range and the standard of proof in such a case shall be by a balance of probabilities.
- 6.7 The applicable standard of proof for the Expert Medical Panel in making its recommendation as regards the athlete's eligibility in accordance with the criteria in 6.5 above shall be to the comfortable satisfaction of the Panel.
- 6.8 If the Expert Medical Panel's recommendation is that the athlete does not meet the criteria in paragraph 6.5, it shall provide its reasons in writing and may further recommend:
- 6.8.1 conditions under which it would be acceptable for the athlete to compete in women's competition; and
 - 6.8.2 a schedule of monitoring of the athlete's prescribed medical treatment with a view to the athlete returning to competition once she meets the conditions so determined (Return to Competition Monitoring).

Chapter 7 IAAF decision on Eligibility

- 7.1 The recommendation of the Expert Medical Panel shall be communicated in writing to the IAAF Medical Manager who shall decide upon the athlete's eligibility taking account of the recommendation that has been made.
- 7.2 The decision of the IAAF regarding the athlete's eligibility shall be notified to the athlete and her designated physician and, where necessary, to her National Federation. The IAAF decision may be appealed exclusively to CAS in accordance with the provisions of IAAF Rule 60.23 and following.
- 7.3 The IAAF may decide that the athlete shall be eligible to compete in women's competition subject to meeting any conditions for competition as recommended by the Expert Medical Panel. In this event, the athlete shall not be eligible to compete until such conditions have been met, including her compliance with any schedule of Return to Competition Monitoring.
- 7.4 The athlete shall be responsible for complying with her prescribed medical treatment during the period of Return to Competition Monitoring and shall provide the IAAF Medical Department with satisfactory evidence of such compliance, as it may request. The IAAF Medical Manager may consult with the Chairman of the Expert Medical Panel at any stage during this period as he considers necessary.
- 7.5 At the end of the period of Return to Competition Monitoring, the athlete's case shall be referred back to the Expert Medical Panel to make a recommendation on the athlete's return to competition. For this purpose, the IAAF Medical Department shall provide the Expert Medical Panel with all evidence of the athlete's compliance with her prescribed medical treatment, including the results of any tests that have been conducted as part of such treatment during the Return to Competition Monitoring period.
- 7.6 Upon receipt of the athlete's further medical information and data, the Expert Medical Panel shall make a recommendation on the athlete's return to competition provided that it is satisfied that the athlete has met the conditions for return that it previously determined. If the athlete meets the conditions determined by the Expert Medical Panel, the athlete shall be notified by the IAAF that she is eligible to compete in women's competition with immediate effect. If the athlete does not meet the

conditions determined by the Expert Medical Panel, the athlete shall be notified by the IAAF that she is not eligible to compete until such time as the conditions are met. In this event, the Expert Medical Panel may recommend that the athlete undergoes a further period of Return to Competition Monitoring before reviewing her case again.

- 7.7 The athlete's return to competition shall in each case be subject to ongoing monitoring by the IAAF to ensure that the athlete is eligible to compete in future competitions in compliance with the conditions determined by the Expert Medical Panel (Competition Monitoring). The Expert Medical Panel may determine in this regard a minimum periodicity of Competition Monitoring which may be supplemented by random unannounced testing conducted by the IAAF at any time. For Competition Monitoring purposes, the IAAF may collect urine and/or blood samples from the athlete.
- 7.8 If an athlete refuses to be tested by the IAAF for Competition Monitoring purposes or if, when tested, is found not to be compliant with the conditions determined by the Expert Medical Panel, the athlete shall not be eligible to compete in Athletics for a minimum period of 2 weeks and until the Expert Medical Panel is satisfied that she is so compliant.

Chapter 8 Entry into force

- 8.1 These Regulations were adopted by the IAAF Council on 12 April 2011 and shall enter into force on 1 May 2011.
- 8.2 In case of any discrepancy in the interpretation of the English or French texts of these Regulations, the English text shall apply.