

[EXPLANATORY NOTES/Q&A]

What is the change?

In April 2018, the IAAF issued new *Eligibility Regulations for the Female Classification (Athlete with Differences of Sexual Development)*. These new Regulations, which were due to come into effect as from 1 November 2018, replaced the previous *Regulations Governing Eligibility of Females with Hyperandrogenism to Compete in Women's Competition*, which no longer applied anywhere in the sport. The new Regulations were stayed pending a legal challenge to their lawfulness before the Court of Arbitration for Sport (CAS).

On 1 May 2019, the CAS Panel that heard the challenge upheld the Regulations. The IAAF has therefore published version 2.0 of the Regulations on 1 May 2019, which will come into effect as from 8 May 2019.

Why has the IAAF issued these Regulations?

As the Court of Arbitration for Sport ('CAS') Panel recognised in Chand v IAAF & AFI (CAS 2014/A/3759), men have significant advantages in size, strength and power over women, due in large part to men's much higher levels of circulating testosterone from puberty onwards. Because of the impact that such advantages can have on sporting performance, it is generally accepted that competition between male and female athletes would not be fair and meaningful, and would risk discouraging women from participation in the sport.¹ Therefore, in common with many other sports, the IAAF has created separate competition categories (or 'classifications') for male and female athletes.

As the CAS Panel also accepted, however, while biological sex is an umbrella term that includes distinct aspects of chromosomal, gonadal, hormonal and phenotypic sex, each of which is fixed and all of which are usually aligned into the conventional male and female binary, some individuals have congenital conditions that cause atypical development of their chromosomal, gonadal, and/or anatomic sex (known as differences of sex development, or 'DSDs', and sometimes referred to as 'intersex').² Such individuals may have levels of circulating testosterone well above the normal female range, into and even exceeding the normal male range.

The CAS Panel ruled that it is up to the IAAF to decide, based on a careful consideration of the available evidence (including the scientific evidence of the extent of the performance advantage that such elevated testosterone levels confer), what conditions (if any) need to be placed on the participation of DSD athletes in the female classification in order to preserve fair and meaningful competition in that classification.

Having gathered and analysed that evidence, the IAAF decided that the previous Hyperandrogenism Regulations needed to be rewritten, to narrow their scope to certain track events, and to strengthen the restrictions applicable to athletes with DSDs participating in those events. The result is these new Regulations, which seek to facilitate the participation in the sport of athletes with DSDs on terms that preserve fair and meaningful competition in the female classification.

¹ There is a substantial (on average, 10-12%) sex difference in athletic performance.

² As a result, some national legal systems now recognise legal sexes other than simply male and female (for example, 'intersex', 'X', or 'other').

What is the evidence on which these new Regulations are based?

Most females (including elite female athletes³) have low levels of testosterone circulating naturally in their bodies (0.12 to 1.79 nmol/L in blood); while after puberty the normal male range is much higher (7.7 – 29.4 nmol/L). Absent a DSD or a tumour, no female would have serum levels of testosterone of 5 nmol/L and above, but individuals with DSDs can have very high levels of natural testosterone, extending into and even beyond the normal male range.⁴

There is a broad medical and scientific consensus that if these individuals are sensitive to androgens (i.e., they have properly-functioning androgen receptors), such very high levels of natural testosterone can increase their muscle mass and strength, as well as their levels of circulating haemoglobin, and so significantly enhance their sporting potential.⁵

Experts consulted by the IAAF have gathered and reviewed all of the published evidence and data, which indicates that increasing the level of circulating testosterone from the normal female range to the normal male range leads to increased muscle mass and strength and higher haemoglobin levels. In particular, increasing testosterone levels in women from 0.9 nmol/L to just 7.3 nmol/L increases muscle mass by 4% and muscle strength by 12-26%; while increasing it to 5, 7, 10 and 19 nmol/L respectively increases circulating haemoglobin by 6.5%, 7.8%, 8.9% and 11% respectively. Taking all available knowledge and data into account, the experts estimate that the ergogenic advantage in having circulating testosterone levels in the normal male range rather than in the normal female range is greater than 9%.⁶

³ See Bermon et al, *Serum Androgen Levels in Elite Female Athletes*, J Clin Endocrin Metab, doi: 10.1210/jc.2014-1391

⁴ See Handelsman, Hirschberg and Bermon (2018), *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, Endocrine Reviews, Volume 39, Issue 5, 1 October 2018, pp. 803–829.

⁵ See, for example, Handelsman, Hirschberg and Bermon (2018), *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, Endocrine Reviews, Volume 39, Issue 5, 1 October 2018, pp. 803–829; Auchus (2017) *Endocrinology and Women's Sports: The Diagnosis Matters*, 80 LAW & CONTEMP. PROBS., no.4, 2017, p.127; Allen (2016) *Hormonal eligibility criteria for 'includes females' competition: a practical but problematic solution*, Horm Res Paediatr 85:278–82; Bermon et al (2015), *Women with Hyperandrogenism in Elite Sports: Scientific and Ethical Rationales for Regulating*, J Clin Endocrinol Metab Jan 14:doi:jc.2014-3603; Ritzén et al (2015), *The regulations about eligibility for women with hyperandrogenism to compete in women's category are well founded. A rebuttal to the conclusions by Healy et al.*, Clin Endocrinol 82:307–8; Sanchez et al (2013), *The New Policy on Hyperandrogenism in Elite Female Athletes is not about "Sex Testing"*, J Sex Res, February, 50:112-115; Wood & Stanton (2012), *Testosterone and Sport: Current Perspectives*, Horm Behav January; 61:147-155; Ballantyne et al (2012), *Sex and gender issues in competitive sports: investigation of a historical case leads to a new viewpoint*, Br J Sports Med, 46:614-617; Gooren (2011), *The significance of testosterone for fair participation of the female sex in competitive sports*, Asian Journal of Andrology 13, 653-654; Hercher (2010), *Gender Verification: A Term Whose Time Has Come and Gone*, J Genet Counsel, 19:551-553; Handelsman and Gooren (2008), *Hormones and sport*, Asian Journal of Andrology, 10, 348-50; Hipkin (1992), *The XY female in sport: the controversy continues*, Br J Sp Med, 27:150156. Cf Healy et al (2014), *Endocrine profiles in 693 elite athletes in the post-competition setting*, Clinical Endocrinology, 81:294-305; Sonksen et al (2014), *Medical and Ethical Concerns Regarding Women with Hyperandrogenism and Elite Sport*, J Clin Endocrinol Metab:doi:10.1210/jc.2014-3206; Sonksen (2016), *Determination and regulation of body composition in elite athletes*, Br J Sports Med, 2016;0;1-13; doi:10.1136/bjsports-2016-096742. See also Huang and Basaria (2017), *Do anabolic-androgenic steroids have performance-enhancing effects in female athletes* Mol Cell Endocrinol. 2018 Mar 15;464:56-64.

⁶ Handelsman, Hirschberg and Bermon (2018), *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, Endocrine Reviews, Volume 39, Issue 5, 1 October 2018, pp. 803–829.

The significant over-representation of DSD athletes in certain events, and their success in those events, provides further indirect but strong corroboration of the above.⁷ In addition, the IAAF has gathered observational data about the difference in performance levels of DSD athletes depending on whether or not their testosterone levels are suppressed, including data showing that suppression of the levels of circulating testosterone of three DSD athletes from 21-25 nmol/L to below 2 nmol/L coincided with their performances decreasing by an average of 5.7%.⁸

This evidence shows clearly that (at least in certain events) DSD athletes with levels of circulating testosterone in the normal male range have a very significant competitive advantage over female athletes with testosterone levels in the normal female range, which justifies requiring DSD athletes to reduce their testosterone levels down to the normal female range in order to compete in the female classification in such events.

What do these Regulations require?

The data indicate that the advantages conferred on certain DSD athletes have been of greatest effect to date in middle distance track events. The Regulations therefore apply only to track events run over distances between 400m to one mile (the **Restricted Events**) at International Competitions.⁹

If a female athlete wishing to participate in a Restricted Event at an International Competition has a DSD that results in levels of circulating testosterone greater than 5 nmol/L, and her androgen receptors function properly, such that those elevated levels of circulating testosterone have a material androgenising effect¹⁰ (a **Relevant Athlete**), she must reduce those levels down below 5

⁷ Bermon et al (2014), *Serum androgen levels in 1058 elite female athletes*, J. Clin. Endocrinol. Metab. 99:4328-4335. In addition, peer-reviewed data from the IAAF World Championships in Daegu (2011) and Moscow (2013) indicate that women in the highest tertile (top 33%) of testosterone levels performed significantly better than women in the bottom tertile (bottom 33%) in the following events: **400m hurdles** (top tertile, with mean T concentration of 1.94 nmol/L, outperformed bottom tertile, with mean T concentration of 0.43 nmol/L, by 3.13%; **400m** (top tertile, with mean T concentration of 7.39 nmol/L, outperformed bottom tertile, with mean T concentration of 0.40 nmol/L, by 1.50%; and **800m** (top tertile, with mean T concentration of 3.28 nmol/L, outperformed bottom tertile, with mean T concentration of 0.39 nmol/L, by 1.60%): Bermon and Garnier (2017), *Serum androgen levels and their relation to performance in track and field: mass spectrometry results from 2127 observations in male and female elite athletes*, Br J Sports Med 2017;0:1-7, additional material at <http://bjsm.bmj.com/content/51/17/1309>.

⁸ Bermon (2017), *Androgens and athletic performance of elite female athletes*, Curr Opin Endocrinol Diabetes Obes 2017;24:246–51.

⁹ Whereas the previous Hyperandrogenism Regulations applied not only to International Competitions, but also to all competitions held under the rules of an Area or member national federation, the new Regulations apply only to International Competitions. As a result, it will only impact on athletes competing at the very highest levels of elite athletics. Those competing below those levels (e.g., in national-level competitions) will not be impacted at all by the new Regulations.

¹⁰ Some DSD athletes have natural mutations that make their androgen receptors completely or partially insensitive to testosterone. If they are completely androgen-insensitive, then the Regulations do not apply to them. If they are partially androgen-insensitive, the Regulations only apply to them if they are sufficiently androgen-sensitive that their elevated testosterone levels have a material androgenising effect. As under the previous Regulations, this is to be assessed by an expert independent medical panel based on physical evaluation and endocrine testing, but with the benefit of any doubt on the issue to be resolved in favour of the athlete (whereas under the previous Regulations the burden was stated to be on the athlete to

nmol/L for six months (e.g., by use of hormonal contraceptives) before competing in such events, and must maintain them below that level until she no longer wishes to participate in Restricted Events at International Competitions.

No other measures are required. In particular, surgical anatomical changes are not required in any circumstances (just as they were not required under the previous regulations).

Why do the new Regulations only apply to 'Restricted Events'?

Based on the evidence referred to above, it appears that these events (track events run over distances between 400m to one mile) are where the most performance-enhancing benefits can be obtained from elevated levels of circulating testosterone, i.e., both from the extra strength and power derived from the increases in muscle mass and strength, and from the extra oxygen transfer and uptake derived from the increased haemoglobin in the blood. Therefore, taking a conservative approach, the new Regulations only apply to such events.

However, the revised Regulations expressly confirm that the IAAF Health & Science Department will keep this under review. If future evidence or new scientific knowledge indicates that there is good justification to expand or narrow the number of events affected by the Regulations, it will propose such revisions to the IAAF Council.

Is the IAAF questioning the sex or gender identity of female athletes with DSDs?

No. These Regulations exist solely to ensure fair and meaningful competition within the female classification, for the benefit of the broad class of female athletes. In no way are they intended as any kind of judgement on or questioning of the sex or the gender identity of any athlete. To the contrary, the IAAF regards it as essential to respect and preserve the dignity and privacy of athletes with DSDs, and therefore it will continue to handle all cases arising under these Regulations in strict confidence.

The new Regulations also include an express warning that anyone who breaches confidentiality, or harasses or stigmatises an athlete, or infringes her dignity or her privacy, will be subject to disciplinary sanction under the IAAF Integrity Code. In particular, persecution or campaigns against athletes simply on the basis that their experience does not conform to gender stereotypes are unacceptable.

What other protections are there for athletes with DSDs?

The CAS Panel in Chand v. IAAF & AFI specifically noted that the Hyperandrogenism Regulations were administered by the IAAF in confidence and with care and compassion, and that they could benefit athletes by identifying underlying medical conditions that require urgent treatment. The IAAF will maintain exactly the same approach under the new Regulations.

In particular, the new Regulations re-affirm that only the IAAF Medical Manager may initiate an investigation in relation to any athlete, and only on reasonable grounds based on information from reliable sources, to avoid the risk of improper 'witch-hunts' of athletes based merely on physical appearance. In addition, to support the existing provisions requiring informed consent from the athlete at every stage of the process, a new provision has been included for the appointment of an

prove that due to androgen resistance she derives no competitive advantage from her elevated testosterone levels).

athlete ombudsman to assist the athlete in understanding the regulations and her options under them.

Furthermore, any case arising under the revised Regulations will not be handled by the athlete's national federation, but instead will be handled by the IAAF Medical Manager and the panel of independent medical experts appointed by the IAAF (with the IAAF covering the costs). This will avoid any risk of improper application of the Regulations at national level due to lack of understanding/resources, as well as the risk of inconsistent application of the Regulations by different national federations.

What if an athlete with a DSD does not wish to have to comply with the Regulations?

An athlete with a DSD who did not wish to have to comply with the Regulations would not be barred from competing in the sport. To the contrary, without suppressing her elevated levels of circulating testosterone, she would still be entitled to compete:

- (1) in the female classification:
 - a. at any competition that is not an International Competition: in any event, without restriction; and
 - b. at International Competitions: in any discipline other than track events between 400m and a mile; or
- (2) in the male classification: at any competition at any level, in any discipline, without restriction; or
- (3) in any 'intersex' (or similar) classification that the event organiser may offer: at any competition at any level, in any discipline, without restriction.

Why do the new Regulations not refer to athletes with hyperandrogenism?

It would be misleading to suggest that the Regulations apply to all female athletes with hyperandrogenism, because in normal medical parlance that would include women with polycystic ovary syndrome (PCOS), but the levels of circulating testosterone of such athletes would be less than 5 nmol/L, and therefore they will not be covered by the new Regulations.

Why has the limit for circulating testosterone changed from 10 nmol/L to 5 nmol/L?

A rigorous review of the data has established that the normal female range of circulating testosterone in serum is 0.12 to 1.79 nmol/L, and the normal male range is 7.7 to 29.4 nmol/L, while women with PCOS could have circulating testosterone as high as 4.8 nmol/L. Therefore, the only female athletes competing with levels above 5 nmol/L would be intersex/DSD athletes, doped athletes, and athletes with adrenal or ovarian tumours. In addition, (a) below 5 nmol/L, there is limited evidence of any material testosterone dose-response; but (b) an increase in circulating testosterone from normal female range up to between 5 and 10 nmol/L delivers a clear performance advantage (according to the studies, a 4.4% increase in muscle mass and a 12-26% increase in muscle strength, and a 7.8% increase in haemoglobin).¹¹

¹¹ See Handelsman, Hirschberg and Bermon (2018), *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, *Endocrine Reviews*, Volume 39, Issue 5, 1 October 2018, pp. 803–829.

Accordingly, if the Regulations are to do their job of protecting the level playing-field in the female classification, then the threshold needs to be 5 nmol/L, not 10 nmol/L.

Under the new Regulations, all measurements of circulating testosterone levels must be conducted by means of gas or liquid chromatography coupled with mass spectrometry using a validated method.

Why is there now a six-month period during which a Relevant Athlete must keep her testosterone levels below 5 nmol/L before she may compete in Restricted Events at International Competitions?

This requirement has been introduced in order to minimise any lingering advantages that a Relevant Athlete may have from having previously had levels of circulating testosterone well above 5 nmol/L. The normal life-cycle of a red blood cell is about 120 days. Therefore, six months should be enough to see a reduction in haemoglobin following the reduction in circulating testosterone, even if the benefits of increased muscle mass and strength will likely endure to some extent beyond that.

The new Regulations will come into effect only from 8 May 2019. Therefore, female athletes with DSDs are able to start demonstrating compliance with this requirement immediately should they wish to avoid having to stand down from competition once the Regulations come into effect. Compliance with this requirement will be monitored by random testing, and any demonstrated non-compliance will trigger a new 'stand-down' period of six months, during which the athlete will not be able to compete in Restricted Events at International Competitions.

Will Relevant Athletes be eligible to compete at the IAAF World Athletics Championships, Doha 2019?

One of the Eligibility Conditions at clause 2.3 of the Regulations requires a Relevant Athlete to reduce her testosterone levels to below 5 nmol/L for a continuous period of at least six months prior to competition in the female classification in a Restricted Event at an International Competition. Six months from 8 May 2019 (the date that the new Regulations come into force) will expire after the 2019 IAAF World Athletics Championships in Doha have taken place.

However, version 2.0 of the new Regulations contains a special transitional provision that has been introduced by the IAAF to ensure that the delay in the Regulations coming into effect caused by the legal challenge to the Regulations does not prejudice Relevant Athletes.

The special transitional provision, at clause 2.3(b), states that a Relevant Athlete who reduces her blood testosterone to below five (5) nmol/L for a continuous period starting from 8 May 2019 to 28 September 2019 will be deemed to have met this eligibility condition to compete in the female classification in a Restricted Event at the IAAF World Athletics Championships, Doha 2019.

All elite athletes have natural genetic and/or biological advantages (e.g., height, lung capacity, etc). The IAAF does not stop them reaping the benefits of those advantages, so why deny DSD athletes the benefit of their natural levels of circulating testosterone?

The IAAF divides competition into male and female classifications because male athletes have clear performance advantages in terms of size, strength and power, as a result (in particular) of increased lean body mass and increased serum haemoglobin, which in turn is due mainly to the fact that, starting from puberty, they produce 10-30 times more testosterone than women. As noted above, the CAS has found that this difference justifies protecting female athletes from competition from male athletes.

Where a female athlete has a DSD that gives her levels of circulating testosterone in the male range, and she is sufficiently androgen-sensitive for those levels to have a material androgenising effect, e.g., increasing her lean body mass and/or her levels of serum haemoglobin, then treating like cases alike means requiring her to reduce her testosterone levels to below 5 nmol/L in order to compete in the female classification in the most obviously affected events.

To the best of our knowledge, there is no other genetic or biological trait encountered in female athletics that confers such a huge performance advantage. And certainly the sport has never considered that competing against an athlete with any other type of genetic or biological advantage was not fair and meaningful. For example, it does not see the need for weight categories or height categories (or any other categories, other than age) in order to preserve fair and meaningful competition. Instead, it regards such factors as part of the combination of natural talent and sacrifice and determination that the sport seeks to celebrate. If that were to change in the future, e.g., if height were deemed to confer an unfair advantage in a particular event, then it might become appropriate to introduce height classifications. Until then, however, it is appropriate to treat such 'natural' advantages differently from the advantage that a female athlete with a DSD gets from her elevated levels of circulating testosterone.

What is the IAAF's position in relation to trans athletes?

The IAAF also has an inclusive approach to the participation of trans athletes in sport, currently reflected in its Regulations Governing Eligibility of Athletes Who Have Undergone Sex Reassignment to Compete in Women's Competitions (see <https://www.iaaf.org/about-iaaf/documents/medical>). It is currently reviewing and updating those regulations in light of the evidence identified above and in light of the learnings from the IOC's 2015 Consensus Meeting on Sex Reassignment and Hyperandrogenism (https://stillmed.olympic.org/Documents/Commissions_PDFfiles/Medical_commission/2015-11_ioc_consensus_meeting_on_sex_reassignment_and_hyperandrogenism-en.pdf), and expects to issue updated regulations on this topic in the coming months.

Who is the contact at the IAAF for further information?

Athletes, athlete support personnel and National Federation officials with questions about the application of the new Regulations may contact the IAAF Medical Manager, as follows:

IAAF Medical Manager
Health and Science Department
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