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ARTICLE

The regulation of threshold levels for prohibited substances in the world anti-doping program

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Abstract
Technological advancements in the equipment and laboratories used by anti-doping bodies means that minute levels of prohibited substances can be detected in an athlete's blood or urine. This had led to an increase in athletes testing positive for prohibited substances where the quantity of that substance in the athlete's sample is very low. This article will consider the role that decision limits and minimum reporting levels play with respect to prohibited substances identified in the World Anti-Doping Program. Recent CAS awards are analyzed to determine whether, and how, the issue of threshold requirements for prohibited substances should be further regulated.

Keywords Doping · Anti-doping · Threshold · Decision limit · Minimum reporting level · World anti-doping code

1 Introduction

The World Anti-Doping Program is designed to protect an athlete's right to participate in doping-free sport. It pursues this goal through a series of documents, including the *World Anti-Doping Code* ('*Code*'), International Standards, and Technical Documents and Letters, that when read together aim to educate and then deter, detect and enforce anti-doping rule violations. The stated rationale for the *Code* is to protect the intrinsic value of sport, the integrity of sport and the health of athletes.[1] This triparte raison d'être is preserved through a list of anti-doping rule violations and their concomitant sanctions. Sometimes an athlete may be found to have very low levels of a prohibited substance in their system. In cases where the quantity of a prohibited substance in an athlete's system is not performance enhancing, or injurious to health, the fundamental rationale for imposing an anti-doping rule violation under the *Code* is arguably lessened.[2]

'Decisions Limits' and 'Minimum Reporting Levels' with respect to certain prohibited substances represent a response from the World Anti-Doping Agency ('WADA') to the increased technological sophistication of doping control procedures. Both Decision Limits and Minimum Reporting Levels implicitly acknowledge that even the most fastidious of athletes may inadvertently ingest a prohibited substance through contaminated supplements, pharmaceutical products or different types of meat. The challenge for the World Anti-Doping Program is to acknowledge, recognize and appropriately sanction those cases where an athlete's pharmacokinetic data is consistent with inadvertent doping. An athlete engages in inadvertent doping when a prohibited substance is found in their system, but the athlete did not intentionally / deliberately take the substance and was not negligent with respect to how the substance entered their system.[3] Great care must be taken to ensure that these athletes are sanctioned in a way that reflects their moral culpability.

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[1] *Code* (2021), p. 13.
[2] Viret (2019), pp. 90–91.
[3] Duffy and O'Brien (2021), p. 147; *Code* (2021), art. 10.2.3.

This challenge for the World Anti-Doping Program occurs in a context where the doping methods of cheating athletes are also increasing in sophistication.[4] Where an athlete has a low level of a prohibited substance in their system, there may be more sinister explanations for that result. Perhaps the athlete has engaged in systematic micro-doping, or the athlete has been tested towards the end of a doping cycle, where the prohibited substance has largely cleared their system. In these circumstances, Decisions Limits and Minimum Reporting Levels may have the unwarranted effect of shielding a morally culpable athlete. The context is further complicated by the lack of firm science with respect to certain prohibited substances. In some cases, it simply is not clear what level of a prohibited substance is required in an athlete's system to produce a performance-enhancing effect. Given the ethical issues surrounding the testing of certain prohibited substances, it is not viable for scientists to run randomized control tests to ascertain the performance-enhancing effects of some substances on athletes. This means that expert evidence provided before first-instance doping panels and bodies like the Court of Arbitration for Sport ('CAS'), is often heavily caveated and based on assumptions about the effect of a prohibited substance at a given quantity, on a particular athlete.[5]

Decision Limits and Minimum Reporting Levels therefore play an important (and sometimes controversial) role in the effective operation of the World Anti-Doping Program. This article considers the historical evolution of Decision Limits and Minimum Reporting Levels, and their role with respect to anti-doping rule violations. As will be seen throughout this article, the introduction of such threshold quantities has developed in piecemeal fashion, and recent case studies (Australian swimmers Shayna Jack and Brenton Rickard) suggest ongoing issues with the identification of prohibited substances that should have a Decision Limit or Minimum Reporting Level, and the quantity at which that level should be set. This article ultimately concludes that WADA should proactively and prospectively assess *every* prohibited substance on the prohibited list, to see if they should be subject to a DL or an MRL. Where a threshold should be implemented, its quantitative level should be set using expert advice. Technical Documents relating to Decision Limits and Minimum Reporting Levels would then need to be appropriately updated, with an ongoing commitment to update these documents on (at least) an annual basis.

2 Consideration of substance quantity within the world anti-doping program

The *Code* is the primary document of the World Anti-Doping Program. The *Code* was first produced by the WADA in 2003 with the explicit aim of protecting an athlete's right to participate in doping-free sport and to ensure a unified international approach to preventing doping in elite sport.[6] The *Code* has been through four iterations (the current version in force is 2021) however the strict liability of athletes who have a prohibited substance present in their system has remained relatively unchanged. With few exceptions, the presence of *any* reported quantity of a Prohibited Substance in an athlete's sample constitutes an anti-doping rule violation ('ADRV').[7] This article will outline these exceptions and consider their contribution to an effective and fair anti-doping regime.

2.1 The world anti-doping program

WADA's Anti-Doping Program consists of the *Code* itself, as well as a set of eight International Standards and a series of Technical Documents which signatories must adhere to in order to maintain *Code* compliance.[8] Among the International Standards are the *Prohibited List* and the *International Standard for Laboratories* ('*ISL*'). Integral to the *ISL* is a series of WADA-issued Technical Documents and Technical Letters which provide direction on analysis, interpretation and reporting of results or specific laboratory procedures.[9] The regime renders an athlete responsible for the presence in their sample of any prohibited substance identified on the *Prohibited List*.[10] Samples are analyzed by WADA-approved laboratories, which must adhere to the *ISL*. Laboratories that detect the presence of any quantity of a prohibited substance in a sample report an Adverse Analytical Finding ('AAF'),[11] unless one of two relevant exceptions is triggered. A report of an AAF establishes a reported quantity of a prohibited substance present in a sample, which usually (but not always) constitutes an ADRV on the part of the athlete.[12]

[4] Niggli (2017); Viret (2019).

[5] This concern is magnified in situations where a party simply cannot afford the expense of hiring an expert to provide a professional opinion. See Star and Kelly (2022); Star and Kelly (2020).

[6] *Code* (2021), p. 9.

[7] *Code* (2021), art. 2.1.3.

[8] *Code* (2021), p. 10.

[9] *International Standard for Laboratories* (2021), art. 1.1.3.

[10] *Code* (2021), art. 2.1, 4.2.

[11] The term 'Adverse Analytical Finding' is defined in the *Code* (2021) Appendix 1.

[12] *Code* (2021), Articles 2.1.3, 2.1.4. An example where an ADRV would not occur following an AAF, is if the Athlete had an approved Therapeutic Use Exemption for the detected prohibited substance.

2.2 The exceptions

2.2.1 Decision limits

The presence of a prohibited substance in an athlete's system at any detected level may not constitute an AAF if that substance has a Decision Limit ('DL') identified in the *Prohibited List* or a Technical Document.[13] The term 'Decision Limit' is defined by the *Code* as, 'the value of the result for a Threshold Substance in a Sample, above which an Adverse Analytical Finding shall be reported, as defined in the International Standard for Laboratories.'[14] A 'threshold substance' is defined in the *ISL* as:

> an exogenous or endogenous Prohibited Substance, Metabolite or Marker of a Prohibited Substance for which the identification and quantitative determination (e.g., concentration, ratio, score) in excess of a pre-determined Decision Limit, or, when applicable, the establishment of an exogenous origin, constitutes an Adverse Analytical Finding. Threshold Substances are identified as such in the Technical Document on Decision Limits (*TD DL*).[15]

The *ISL* further defines 'threshold' as:

> the maximum permissible level of the concentration, ratio or score for a Threshold Substance in a Sample. The Threshold is used to establish the Decision Limit for reporting an Adverse Analytical Finding or Atypical Finding for a Threshold Substance.[16]

Therefore, in order for this exception to apply a threshold must be established for a substance by the WADA. The threshold is then used to calculate a DL, which is expressly identified in the *Technical Document on Decision Limits for the Confirmatory Quantification of Exogenous Substances by Chromatography-Based Analytical Methods* ('*TD DL*').[17] Laboratories must use a quantitative analytical method to measure the precise value of the result for the threshold substance in the sample. Unless this value is above the DL, it will not result in an AAF.

In the 2022 *TD DL*, there are eight threshold substances, spanning classes S3 (Beta-2 Agonists), S6 (Stimulants), S7 (Narcotics), and S8 (Cannabinoids).[18] All of these threshold substances are classified as 'specified substances' in the *Code* and *Prohibited List*, meaning that such substances are more likely to have been consumed for a purpose other than performance enhancement.[19]

2.2.2 Minimum reporting limits

All other substances on the *Prohibited List* are known as 'non-threshold substances', defined by the *ISL* as 'a substance listed on the *Prohibited List* for which the identification, in compliance with the *Technical Document on Chromatographic-mass Spectrometric Identification Criteria* ('*TD IDCR*') or other applicable Technical Document(s), constitutes an Adverse Analytical Finding.'[20] The *Code* allows the *Prohibited List*, *ISL* or a Technical Document to establish special reporting criteria for certain non-threshold substances.[21] The most significant example of such criteria is the set of Minimum Reporting Levels ('MRL') for specific non-threshold substances prescribed in the WADA *Technical Document on Minimum Required Performance Levels and Applicable Minimum Reporting Levels for Non-Threshold Substances analyzed by Chromatographic-Mass Spectrometric Analytical Methods* ('*TD MRPL*').[22] For non-threshold substances subject to an MRL, the role of the laboratory is to consider the presence or absence of the substance over an established level. If the estimated concentration of the substance in the sample is below the established MRL, it should not be reported as an AAF.[23]

There are currently over 30 individual substances[24] listed in the *TD MRPL* that have an MRL (in addition to some entire classes of substance). The vast majority of these substances are in the category of 'specified substances', although some 'non-specified' substances (including some anabolic agents) have also been given an MRL.[25]

[13] *Code* (2021), art 2.1.3; *Technical Document on Decision Limits for the Confirmatory Quantification of Exogenous Substances by Chromatography-Based Analytical Methods* (2021) ('*TD DL*').

[14] *Code* (2021) Appendix 1.

[15] *International Standard for Laboratories* (2021), art. 3.2.

[16] *International Standard for Laboratories* (2021), art. 3.2.

[17] This Technical Document has been updated annually (occasionally biannually) beginning in 2010.

[18] *TD DL* (2022), p 2. There are further substances in the *Prohibited List* where a permissible concentration is provided for, yet these substances are not listed as Threshold Substances in *TD DL*.

[19] *Code* (2021), comment to art 4.2.2.

[20] *International Standard for Laboratories* (2021), art. 3.2.

[21] *Code* (2021), art. 2.1.4.

[22] This document applies, for the most part, to analysis of urine samples. There are other Technical Documents or Letter applicable to specific substances which may also impose an MRL.

[23] *Code* (2021) Appendix 1.

[24] The actual number depends on whether derivates of particular substances are counted as a distinct substance.

[25] These non-specified substances are from class S1 Anabolic Agents (6α-hydroxy-androstenedione; 19-norandrosterone; 19-noretiocholanolone; Boldenone; Clenbuterol; Ractopamine; Zeranol; Zilpaterol), class S4.4 Metabolic Modulators (Meldonium), and class S6 Stimulants (whole class 6.A non-specified stimulants; cocaine).

2.2.3 Comparison between DLs and MRLs

DLs and MRLs are both pre-existing and pre-defined limits that affect whether the presence of a prohibited substance in a sample should be reported as an AAF. The most obvious difference between these two types of limits is that they apply to different prohibited substances. DLs are applied to 'threshold substances', and their existence is acknowledged in the *Code*. The magnitude of the DL is recorded in either the *Prohibited List* or a Technical Document. Established thresholds can prevent athletes from being sanctioned for permissible use of a prohibited substance–that is, there may be overriding health justifications to permit a threshold substance to be used by an athlete in certain quantities, whereby no violation occurs. MRLs are applied to 'non-threshold Substances', where in the absence of an MRL, the presence of a prohibited substance in a sample at any concentration would ordinarily constitute an ADRV. The rationale behind the establishment of MRLs for certain non-threshold substances is not always documented, although more modern Technical Letters are much clearer with respect to the reasons why a *MRL* may be introduced, raised or lowered with respect to a particular prohibited substance.

As an example, the Beta-2 Agonist tretoquinol (2018) and a group of six diuretics (2021) had MRLs set after being identified as ingredients or contaminants of prescription and over-the-counter oral pharmaceutical products.[26] The MRL for tretoquinol was set to avoid the reporting of an AAF based on the inadvertent use of tretoquinol-containing medications.[27] The setting of an appropriate MRL for diuretics is challenging, because they may be used to mask the presence of other prohibited substances in an athlete's system. Ideally the MRL for certain diuretics is set at a level below that needed to effectively mask the presence of a prohibited substance, but above the level that might be expected if an athlete were to inadvertently consume a contaminated, legitimate pharmaceutical product.[28] *Technical Letter 24* captures the purpose of setting an MRL for a prohibited substance when it states that, '[setting an MRL] will minimize the risk of sanctioning Athletes who test positive due to the use of contaminated medications, without undermining the fight for clean sport.'[29]

The two limits are further distinguished by the preciseness with which they are established and measured. DLs are determined by applying a mathematical formula proscribed in the *TD DL*.[30] WADA first establishes a threshold ($\underline{T}$) for a particular prohibited substance. A guard band (g) is then added to the threshold level, to determine the Decision Limit for the substance. Given that there is a margin of error involved in the measurement of a prohibited substance in an athlete's sample, the guard band is designed to allow for this error. The formula for a DL is:

$$DL = \underline{T} + g$$

(Decision limit = threshold level plus guard band).

This formula then permits a statistical confidence interval to be performed, ensuring that when a sample contains a concentration of a prohibited substance above the DL, then the laboratory can be at least 95% confident that the level of the substance exceeds the threshold.[31] Laboratories must then undertake analytical testing procedures to ascertain the exact level of the substance in the sample, and compare this value to the DL for the substance.[32]

The existence and level of MRLs for particular prohibited substances is informed by research conducted by WADA working groups or laboratories.[33] An AAF is reported if the prohibited substance is found in a sample at a concentration that exceeds the MRL. A margin of error is again built into the process, and a confirmation procedure involves measuring the sample concentration against a single point calibration sample at 120% of the MRL.[34] An AAF is only reported if the analyte signal in the sample is greater than the analyte signal in the 120% calibration sample.

In summary, both DLs and MRLs are an acknowledgment that an athlete may have low levels of a prohibited substance in their system, without being at (moral) fault. The procedures and equipment used to test samples for the presence of a prohibited substance are sophisticated, but they are not without a small degree of measurement error. This means that the *non-existence* of an MRL for a non-threshold substance, the *level* set as an MRL for a particular substance, and a laboratory's *estimated* concentration of a prohibited substance in a sample may all be controversial topics in an anti-doping case. The World Anti-Doping Program rather bluntly addresses these issues, by stating in the *Code* that WADA's decision to implement an MRL, its decision to set an MRL, and the possibility of error in a laboratory statistical estimate are not subjects that can be challenged by an athlete.[35]

[26] *Technical Letters* 16 1.0 and 24 1.0.

[27] *Technical Letter* 16 1.0.

[28] *Technical Letter* 24 1.0.

[29] *Technical Letter* 24 1.0, p. 1.

[30] *TD DL* (2022) v1.0.

[31] *TD DL* (2022) v1.0, p. 2.

[32] *International Standard for Laboratories* (2021), art. 5.3.6.2.2; *TD DL* (2022) v1.0.

[33] As an example, see *Technical Letter* 16 1.0, *Explanatory Notes on the 2011 Prohibited List* S3, p. 2.

[34] *TD MRPL* (2022), section 5.0.

[35] *Code* (2021), comment to art. 3.2.1.

2.3 The history of thresholds, decision limits and minimum reporting levels

2.3.1 Thresholds

From its first version in 2003, the *Code* has permitted an exception to the strict liability of Article 2.1 for any substance that has a quantitative threshold identified in the *Prohibited List*.[36] The original 2004 *Prohibited List* included thresholds for the stimulants cathine, ephedrine and methylephedrine which still exist today.[37] Another stimulant, pseudoephedrine, was specifically not prohibited until 2010 when it was included in the *Prohibited List* and allocated a threshold that remains unchanged to the present.[38] Pseudoephedrine is commonly used in medications that treat respiratory conditions and common cold symptoms.

Thresholds for asthma medications salbutamol and formoterol have also appeared in the *Prohibited List* since 2004 and 2012 respectively. These substances were, and continue to be, part of a small group of prohibited substances that have been given a quantified threshold within the *Prohibited List*. Thresholds for a number of other prohibited substances first began to appear in the original 2004 *Technical Document on Minimum Required Performance Limits* (*'TD MRPL 2004')*.[39] This means that almost from the beginning of the World Anti-Doping Program, the *Prohibited List* and *Technical Documents on Minimum Required Performance Limits* have coexisted and provided thresholds for certain prohibited substances. International Standards were incorporated by reference into the first version (2003) of the *Code*.[40] and Technical Documents, once promulgated, became part of the *International Standard for Laboratories*.[41]

2.3.2 Decision limits

In 2010 the first *Technical Document on Decision Limits* was published, containing thresholds for particular threshold substances, as well as a DL for each listed substance.[42] The term 'Decision Limit' had not previously been used in any World Anti-Doping Program documents. As mentioned above, the purpose of a DL is to acknowledge a margin of error involved in the measurement of a prohibited substance in an athlete's sample. This is achieved by adding a guard band to the threshold value of the prohibited substance. Historically, the reporting of an AAF with respect to threshold substances was always required to consider measurement uncertainty.[43] The advent of DLs gave a label and increased sophistication to measurement uncertainty and how it should be treated when analyzing an athlete's sample results.

The first official mention of DLs in the *Code* did not occur until its third iteration in 2015,[44] but compliance with Technical Documents (which named and recognized DLs in 2010) has meant that the concept of DLs was incorporated by reference into the *Code* from 2010.[45] A year earlier in the 2009 version of the *Code*, the definition of 'adverse analytical finding' was amended to explicitly specify that reporting from a laboratory must be done in compliance with all Technical Documents.[46] The timing of these changes suggest that there was some appreciation from WADA that consistent use of terminology across different documents that make up the World Anti-Doping Program is desirable. There has been a gradual move towards explicit mention of key anti-doping terms in the *Code* itself (as opposed to existing in *Technical Documents* or the *ISL* only), and mention of those terms in *context*. As an example, the 2015 version of the *Code* mentions the phrase 'Decision Limits' only once, with respect to methods for establishing anti-doping facts and presumptions.[47] In the 2021 version of the *Code*, it is made explicitly clear that substances subject to DLs are an exception to the strict liability of Article 2.1, which normally does not permit any quantity of a prohibited substance in an athlete's system.[48]

Even if a prohibited substance is assigned a DL through a *Technical Document on Decision Limits*, it may subsequently be removed to a different Technical Document due to unique issues arising from the measurement of that substance in an athlete's sample. 19-norandrosterone and epitestosterone, two of the original threshold substances to be assigned DLs, have since been referred to separate technical documents which govern their testing and reporting.[49] Controversy has existed over the reliability of a threshold for norandrosterone since as early as 2007.[50] It appears that the WADA eventually deemed this substance unsuitable for the simple application of a threshold, as the processes outlined in its technical document are more complex than the simple application of a DL.[51] In 2014, epitestosterone was amalgamated into a different technical document as a marker

[36] *Code* (2004), art. 2.1.2.

[37] *Prohibited List* (2004), p. 1.

[38] *Prohibited List* (2010), p. 8.

[39] *TD MRPL* (2004), p. 2.

[40] *Code* (2004), p. 2.

[41] *International Standard for Laboratories* (2004) v1.0, p. 5.

[42] *TD DL* (2010), p. 2.

[43] *International Standard for Laboratories* (2004), art. 5.2.4.3.2.3.

[44] *Code* (2015), art. 3.2.

[45] *TD2010DL*.

[46] *Code* (2009), Appendix 1.

[47] *Code* (2015), art. 3.2.

[48] *Code* (2021), art. 2.1.3.

[49] *TD2021NA*, *TD2021EEAS*, *TD2021CG/LH*. See also *TD2021DL*, p. 1 (Summary of modifications).

[50] McLaren (2007), p. 17.

[51] *TD2021NA*.

contributing to an athlete's steroid profile, as opposed to having its own standalone threshold.[52]

The treatment of both of these prohibited substances highlights two main factors. First, increased understanding of prohibited substances, and sophistication of laboratory testing procedures, may mean that it is appropriate to modify the quantitative value of a DL, or impose additional testing requirements in addition to assessment of a DL. DLs are not a 'set and forget' phenomena. Second, when a substance is moved from the *TD DL* to a separate Technical Document, then there should be a note or other logical way to determine that the prohibited substance is still a threshold substance, subject to threshold testing by laboratories. In the 2022 *TD DL* and the 2022 *Prohibited List*, there is no indication that either Norandrosterone or Epitestosterone are threshold substances. This only becomes apparent if an interested party is aware that separate Technical Documents govern the testing of these particular substances.[53] This itself is not a large problem, but if a substance has previously been included in the *TD DL*, and then has been moved to another document (whilst still remaining a threshold substance), then a note or reference should be made, and kept in the *TD DL* to this effect.

Three brief examples illustrate the flexibility that has (and should) be applied to DLs attached to particular prohibited substances. Formoterol was assigned a threshold and DL in the 2012 *TD DL*, after an allowed dosage was indicated in the 2012 *Prohibited List*.[54] Both the threshold and DL for Formoterol were raised in 2013 in line with an increased allowed dose in the 2013 *Prohibited List*.[55] Glycerol was added to the 2012 *TD DL*, but disappeared in 2018 after being removed from the *Prohibited List* altogether.[56] Carboxy-THC has been present in the *TD DL* since inception, but had its DL (but not threshold) raised in 2012. In 2013, the threshold for Carboxy-THC was increased by ten times the initial value (from 15 ng/ml to 150 ng/ml).[57] These examples again demonstrate the flexibility that WADA has to add, alter or remove a threshold and concomitant DL with respect to a particular prohibited substance.

Frustratingly, few of the changes relating to prohibited substances in the *TD DL* have been explained (through official WADA documentation or the *TD DL* itself). One can guess that changes to DLs are made due to new knowledge about when a particular level of a prohibited substance is likely to become performance enhancing, or injurious to health. Without a more transparent articulation as to why changes are being made with respect to threshold levels, there can be confusion as to why some prohibited substances have a DL, where others do not.

In particular, the variation in status between different beta-2 agonists (bronchodilators) used to treat asthma would be puzzling to 'lay' readers. In the first *TD DL* (published in 2010), Salbutamol alone was assigned a threshold (and DL), consistent with an allowed dosage specified in the *Prohibited List*.[58] Upon release of the 2011 *Prohibited List*, WADA indicated that thresholds for other beta-2 agonists were being developed.[59] This work appeared to gain momentum when an allowed dosage for Formoterol appeared in the 2012 *Prohibited List* followed by a threshold and associated DL in the same year.[60] A third beta-2 agonist, Salmeterol, has been treated unusually in that it was identified in the 2010 *Prohibited List* as being an exception to the beta-2 agonist prohibition, so long as the athlete had a therapeutic use exemption for its use. It was not until the 2017 *Prohibited List* that a daily maximum level of inhaled salmeterol was prescribed. For some reason, Salmeterol has been classified as a non-threshold substance, and a note in the 2015 *Technical Document on Minimum Required Performance Levels* stated that Salmeterol should not be reported at levels below 10 ng/ml.[61] It seems strange that some beta-2 agonists are classified as threshold substances (with a DL) and others are classified as non-threshold substances (sometimes with an MRL). The authors have not been able to locate any WADA documentation that addresses why beta-2 agonists have been classified differently, depending on the precise substance involved.[62]

2.3.3 Minimum reporting levels

While the concept of Minimum Reporting Levels was officially incorporated into the *Technical Document on Minimum Required Performance Levels* in 2022,[63] the term had been introduced in other documents in the months prior to its publication. 'Minimum Reporting Level' was officially defined in the *Code* for the first time in 2021.[64] The term

[52] *TD2014EAAS*; Finel and Kuurane (2006), pp. 1–2.

[53] *TD2021NA*, *TD2021EEAS*. A summary of all Technical Documents in force can be found at: https://www.wada-ama.org/en/resources/technical-documents-index.

[54] *TD2012DL*, p. 2; *Prohibited List* (2012), p. 4.

[55] *TD2013DL* p. 2, *Prohibited List* (2013), p. 5.

[56] *TD2012DL*, *Summary of Major Modifications and Explanatory Notes: 2018 Prohibited List,* p. 2.

[57] *TD2013DL*, p. 2.

[58] *TD2010DL*, p. 2, *Prohibited List* (2010), p. 4.

[59] *Explanatory notes on the 2011 Prohibited List*, p. 2.

[60] *Prohibited List* (2012), p. 4; *TD2012DL* p. 1.

[61] *Prohibited List* (2017), p. 4; *TD2015MRPL*, p. 4.

[62] *Prohibited List* (2021), p. 9; *TD2022MRPL*, p. 6. Similarly, an allowed dosage was named for vilanterol in 2021 but it was allocated an MRL as opposed to a threshold in 2022.

[63] *TD2022MRPL*; WADA releases four Laboratory Technical Documents for 2022 | World Anti-Doping Agency (wada-ama.org).

[64] *Code* (2021), Appendix 1.

had also appeared in three Technical Letters which assigned official MRLs to a range of substances before the 2022 *TD MRPL* was published.[65] Despite preceding the official incorporation of MRLs into the *TD MRPL*, the levels established were valid upon the commencement of the Technical Letters, which are considered an integral part of the *ISL*.[66] Although the official terminology of 'Minimum Reporting Level' was not incorporated into WADA documentation until late 2020,[67] the concept of a level below which a laboratory should not report an AAF has existed in the footnotes of the *TD MRPL* since 2009.[68]

The 2004 *TD MRPL* was created to establish a 'minimum routine detection capability' for WADA-approved laboratories who were testing athlete samples for the presence of prohibited substances.[69] While this document prescribed the lowest measures that laboratories must be able to detect, reporting of an AAF was still possible below the set limits. When it was replaced in 2009, the new version contained recommendations that laboratories should not report an AAF where the quantity of the prohibited substance was below 10% of the MRPL for non-threshold substances banned in-competition only, and not below the MRPL at all for glucocorticosteroids.[70] The 2013 version increased this level to 50% of the MRPL where it remained until the introduction of MRLs in 2022.[71]

The 2022 *Technical Document on Minimum Required Performance Levels* officially names and tabulates all prohibited substances that are subject to an MRL. This list of substances is growing, but there is not always a ready found articulation as to why a particular substance has been given an MRL, and the level at which it has been set. Where a Technical Letter exists to further guide laboratories with respect to prohibited substances that have an MRL, *these* TLs often provide a clear and concise explanation for the existence and quantitative level of an MRL.

What is clear from the above, is that thresholds in the form of DLs or MRLs are an evolving and everchanging phenomena. This is appropriate, as new pharmaceutical products and supplements also bring with them the possibility of contamination.[72] Depending where in the world an athlete lives, the possibility of contamination through meat consumption is a real possibility. The WADA's working group on contaminants has recently had its mandate extended until December 2022, with acknowledgment that further extensions may be required.[73] The work of the group is vitally important in an environment where WADA-accredited laboratories are detecting prohibited substances in minute quantities, and sometimes with a precision that exceeds the testing done by manufacturers of pharmaceutical products and supplements. Research continues to indicate that numerous supplements, medications and foods are contaminated by prohibited substances in quantities capable of causing an AAF.[74] The WADA Contaminants Working Group is well aware of these facts, and their challenge (beyond receiving ongoing funding from WADA) is to monitor and respond to those prohibited substances that are highly susceptible to causing inadvertent doping.

The next part of this article will focus on two case studies from Australia, involving high profile swimmers who tested positive to prohibited substances in circumstances that strongly suggested inadvertent doping. These cases highlight some of the difficulties involved with particular prohibited substances that have a high degree of communicability. The role of Decision Limits and Minimum Reporting Levels are considered alongside these case studies, and it is argued that these exceptions have an ongoing important role to play in context-specific instances of inadvertent doping.

3 Case study: Shayna Jack and Ligandrol

3.1 Background to Shayna Jack's ADRV

Shayna Jack is a 24-year-old elite swimmer who has represented Australia at junior and senior level since 2013. She was part of a world-record swim in the 4 × 100 m freestyle relay at the 2018 Commonwealth Games, where Australia won a gold medal.[75] In June 2019, whilst attending an Australian swimming camp, she participated in an out-of-competition doping test. Her sample returned an AAF for the prohibited substance Ligandrol (also known as LGD-4033

[65] *Technical Letter 24* v 1.0 which was effective from June 2021 (published May 2021); *Technical Letter 16* Tretoquinol (published Dec 2020), *Technical Letter 23* Meat Contaminants (published May 2021).

[66] *International Standard for Laboratories* (2021), art. 1.1.3.

[67] *Technical Letter 16* v 3.0 (published 21 Dec 2020), *TD2021DL* (published 21 Dec 2020) and *Technical Letter 15* (published 21 Dec 2020).

[68] *TD2009MRPL,* p. 1.

[69] *TD2004MRPL*, p. 1.

[70] *TD2009MRPL*, p. 1.

[71] One exception was the removing of the S9 class of substances from the recommendation in 2015. The S9 class was instead given a quantified level below which an AAF should not be reported. Salmeterol (50% of the MRPL) was the only substance banned at all times to be included in the recommendations. See *TD2013MRPL* pp. 3–4; *TD2015MRPL.*

[72] *WADA Contaminants Working Group Terms of Reference*: https://www.wada-ama.org/en/resources/governance/contaminants-working-group-terms-reference, p. 1.

[73] *WADA Contaminants Working Group Terms of Reference*: https://www.wada-ama.org/en/resources/governance/contaminants-working-group-terms-reference, p. 1.

[74] Walpurgis et al. (2020), pp. 4, 9–10.

[75] Swimming Australia (2022), Shayna Jack. https://www.swimming.org.au/athletes/shayna-jack. Accessed 27 May 2022.

or VK5211). Ligandrol is classified as a 'non-specified' prohibited substance and is prohibited at all times (in- and out-of-competition).[76] Its presence in an athlete's system at any concentration leads to an initial four-year period of ineligibility, with the possibility of mitigation under the *Code*.[77] Ligandrol is not a substance currently subject to a DL or an MRL. The amount of Ligandrol in Jack's system was described by an expert as "low" and "pharmacologically irrelevant", meaning that it would produce no performance-enhancing effects at that level.

Jack denied that she had taken Ligandrol intentionally,[78] and spent significant time and money attempting to locate the alleged source of the contamination. She was unsuccessful in doing this, and ultimately ended up conceding in the Court of Arbitration for Sport that she did not know how the Ligandrol had entered her system. This meant that Jack could not argue for a reduction of her sanction on the basis of no fault or no significant fault. To establish no/no significant fault or negligence with respect to an ADRV, the athlete must be able to show (on the balance of probability) how the prohibited substance entered their system.[79]

The best-case scenario for Jack was a finding that her ADRV was not committed intentionally.[80] She was successful in arguing that her ADRV was not intentional in her original CAS hearing, and this outcome was later upheld by a CAS Appeal panel.[81] Jack received (and served) a sanction of two years' ineligibility, and has been able to resume competitive swimming from 12 July 2021.[82] She was unable to compete in the 2021 Tokyo Olympic Games as a result of her ineligibility period. It is interesting to note that a number of athletes from different countries have returned positive results for Ligandrol in recent years—some at very low levels.[83] Given the nature and communicability of Ligandrol (discussed below), it is reasonable to expect more anti-doping cases involving this particular prohibited substance.

3.2 What is Ligandrol?

Ligandrol is classified as a 'selective androgen receptor modulator' ('SARM'), which allegedly produces anabolic effects such as an increase in lean muscle mass, without the side-effects of anabolic steroids.[84] Different SARMs are used for different purposes, as they are 'selective' in the type of tissue they target.[85] In a medicinal context, Ligandrol has been trialed for re-building muscle mass in patients recovering from hip surgery.[86] Because these clinical trials showed gains in muscle mass without corresponding increases in body fat, SARMs such as Ligandrol have become popular amongst body builders.[87]

There have been few clinical studies undertaken with the aim of identifying the adverse side-effects of Ligandrol usage (in particular, long-term use).[88] SARMs have not received full clinical approval for human use.[89] The dosage of SARMs advised by fitness industry 'experts' is typically much larger than that which has been encountered in clinical trials. For example, in one trial of Ligandrol, participants were placed in groups to receive either 0mg, 0.1mg, 0.3mg or 1mg doses each day for three weeks. Results of this trial suggest that the drug was well-tolerated with minimal side-effects.[90] These quantities lie in stark contrast to online bodybuilding websites and blogs, which can recommend men take between 10 to 20 mg daily for 8–12 weeks.[91]

Despite its lack of regulatory approval, Ligandrol is advertised for sale on the internet, usually in capsule-form or as a liquid dispensed with a dropper. Australia's Therapeutic Goods Administration has taken compliance action against several Australian companies for 'advertising of unregistered therapeutic goods to consumers' in relation to Ligandrol[92] or SARMs more generally.[93] In Australia, the importation of Ligandrol (even for personal use) is restricted because SARMs are included in the *Poisons Standard*.[94] It is illegal

[76] *Prohibited List* (2022), class S1.2.

[77] *Code* (2021) arts. 10.2, 10.5 and 10.6.

[78] Instagram post: shayna_jack (27 July 2019) https://www.instagram.com/p/B0abPFnAmwW/?utm_source=ig_embed&ig_rid=0bf076e5-63f6-4437-bf7b-7aa8ac101f66.

[79] *Code* (2021) Appendix 1 (definitions of 'no fault or negligence' and 'no significant fault or negligence').

[80] '*Jack original*'; see, also, Duffy and O'Brien (2021).

[81] '*Jack appeal*'.

[82] '*Jack appeal*'.

[83] Lee (2021).

[84] Wheate (2019).

[85] Burmeister et al. (2020), p. 16.

[86] Wheate (2019); Viking Therapeutics (2018).

[87] Wheate (2019); Burmeister et al. (2020), p. 16.

[88] Wheate (2019); Burmeister et al. (2020), p. 16.

[89] Regarding Australia: the substance does not appear (as at 3 Feb 2022) on the 'Australian Register of Therapeutic Goods', see Australian Government, Department of Health—Therapeutic Goods Administration https://www.tga.gov.au/australian-register-therapeutic-goods; see, also, Australian Government, Department of Health—Therapeutic Goods Administration (2019) Consumer story: Tim and selective androgen receptor modulators (SARMs) https://www.tga.gov.au/blogs/tga-topics/consumer-story-tim-and-selective-androgen-receptor-modulators-sarms. Regarding the United States of America: see Burmeister et al. (2020), p. 16; Fragkaki et al (2018).

[90] Basaria et al (2013), pp. 88, 90.

[91] See, for example: Muscle Maker Supplements 2022, https://musclemaker.com.au/lgd-4033-ligandrol; Nanotech Project 2022, https://nanotechproject.org/ligandrol-lgd-4033/.

[92] Australian Government, Department of Health: Therapeutic Goods Administration (2019a).

[93] Australian Government, Department of Health: Therapeutic Goods Administration (2019b).

[94] Australia *Poisons Standard February 2022* (Cth).

to import SARMs without a permit,[95] and possession of a SARM without a prescription is illegal.[96]

As Ligandrol is generally consumed orally, as opposed to intravenously, it is a prohibited substance that is more amenable to inadvertent consumption. A metabolite of Ligandrol has been shown to be detectable in human urine up to 21 days after consumption.[97] Given its route of administration, and the length it can detectably remain in the human body, the communicability of Ligandrol becomes a key issue in determining whether it is a prohibited substance that should have a threshold attached to it.

3.3 Could Jack have inadvertently consumed the Ligandrol?

The degree of communicability of a prohibited substance should be a highly important factor in determining whether a prohibited substance should have a form of threshold attached. In the context of anti-doping, 'communicability' of a prohibited substance refers to the degree in which a prohibited substance can be transmitted from a person, product, or item to another person. It can be a function of both the substance's typical route/s of ingestion and its prevalence in society.

The expert evidence in the Jack case suggested that the quantity of Ligandrol in Jack's system was consistent with the ingestion of a 'pharmacologically irrelevant' dose, within a few days of the anti-doping test.[98] It has been suggested that Ligandrol is transmittable through minute contamination in the form of droplets or powder.[99] This meant that Jack could have been exposed to Ligandrol anywhere… 'a gym, pool, public toilet, hotel, baggage claim at airport etc.'[100] Given the suggested communicability of Ligandrol, and its presence at such a low level in her system, there are two explanations for what may have truthfully occurred. First, Jack may have inadvertently consumed Ligandrol. Second, she may have engaged in micro-doping of Ligandrol, and was tested at a time when the concentration of the substance was at a low point. To refute the second explanation, Jack had her hair tested (at a personal cost of $6000), which indicated no long-term use of a prohibited substance (but of course, this does not eliminate the possibility of one-off use).

In circumstances like these, there is a serious question to be asked as to why athletes are being prosecuted. If it is possible for an athlete to be doing everything that WADA and their national doping organization ask of them, to be fastidious with their food and supplement intake, and still inadvertently dope through exposure to a highly transmittable prohibited substance, then is it fair that the athlete is banned from competition for either two or four years, because they cannot pinpoint the source of the contamination? Further, if the science is under-developed surrounding the communicability of a prohibited substance, or the quantity required to be performance-enhancing, is it fair that this 'lack' disadvantages an athlete who may have the burden of proof to establish non-intentional ingestion of a prohibited substance?[101] The argument being made here is that unless systematic changes are made to World Anti-Doping documents (in the form of DLs and MRLs captured in Technical Documents), then morally innocent athletes will continue to inadvertently dope and fall afoul of the strict liability regime in the *Code*.[102] The sophistication and detection capacity of anti-doping measures will continue to improve. At what point in time do we say that the detection of a non-threshold substance has occurred at such a low level, that it should not constitute an ADRV for an athlete who has not previously returned a positive sample? In the authors' opinion, we have already reached this point in cases such as Shayna Jack's, and the absence of DLs or MRLs for a number of prohibited substances is difficult to comprehend.

An illustration of scientific advances as they relate to the communicability of prohibited substances can be seen in the recent German documentary film, 'Doping Top Secret: GUILTY'.[103] Although this film examined communicability from the perspective of deliberate sabotage by a rival, it nevertheless provided evidence that a person can test positive to a prohibited substance from *skin contact* (e.g., a handshake). In the project, 12 men were touched with a small dose of an anabolic steroid (four substances were trialed) that had been mixed with a 'carrier substance' to facilitate potential absorption into the skin. Urine samples were then tested by the reputable Institute of Forensic Medicine in Cologne. All 12 subjects tested positive to the steroid at various time periods following contact (some in as little as one hour). The carrier substance was only detectable for several days after contact, whilst the steroid was still detectable in one participant's sample after 15 days.[104] Although not part of the experiment, the film alleges that it also would be possible for

[95] Australia *Customs (Prohibited Imports) Regulations 1956* (Cth), sch 4. See, also, Office of Drug Control (2020) Controlled Substances. https://www.odc.gov.au/ws-lps-index.

[96] Australia *Poisons Standard February 2022* (Cth).

[97] Fragkaki et al (2018); Cox and Eichner (2017).

[98] '*Jack original*', para 67.

[99] '*Jack appeal*', para 158.

[100] '*Jack appeal*', para 160.

[101] Recall that an athlete always bears the burden of proving 'no fault or negligence' or 'no significant fault or negligence' under *Code* (2021) arts 10.5 and 10.6. An athlete would also bear the burden of proving a lack of intent, in relation to a 'non-specified substance' only, under *Code* (2021) art 10.2.

[102] Star (2022).

[103] Rbb24 (2021).

[104] Rbb24 (2021), at time 41:55.

a saboteur to apply a protective cream to their own skin to prevent a positive test result, before transferring a prohibited substance to a rival.[105]

These were surprising results, with potentially far-reaching consequences. Beyond the context of sabotage, the ease of communicability of these prohibited substances must put WADA on notice about the enhanced plausibility of inadvertent doping through skin contact. The leader of the doping experiment, Martin Juebner, intends to publish his findings in a peer-reviewed journal.[106] There is now a concomitant need for significant WADA-backed research into the communicability of all substances on the prohibited list. In fairness to WADA, they were quick to acknowledge some of the issues raised by the documentary and acknowledged that the adjustment of DLs for some prohibited substances was an appropriate response to potential contamination cases involving meat and diuretics.[107]

Returning to the facts of the Shayna Jack case, there is still too much that is unknown about Ligandrol. What is clear however, is the ease in which an athlete can ingest the substance, and the many different forums in which an athlete is potentially exposed to the substance. Individual athletes, and athlete representative bodies are right to decry a system that may ban them from competitive sport for two or four years, when they do absolutely everything that WADA asks of them from a risk management perspective. The response from WADA must evolve beyond the catch cry that, 'the fight for clean sport requires such a response'. A more nuanced response would be to:

- Test the communicability of prohibited substances in the prohibited list, prioritized on the basis of those substances which are believed to be prevalent in society or that can be more-easily ingested (Ligandrol being an obvious candidate).
- Assess the typical pharmacokinetic levels of each substance that may be consistent with inadvertent doping, acknowledging individual differences.
- Assess the prevalence of prohibited substances in food, supplements, pharmaceutical products.
- Assess the level of access to prohibited substances through the black market, and the possibility that these substances may be inadvertently transmitted through the community (via people or equipment/facilities).
- Assign additional DLs or MRLs where appropriate.

These tasks are immense, time-consuming and expensive. There is no way to circumvent this reality. From an athlete standpoint, it is fair to suggest that the *balanced* fight for clean sport requires such a response from the WADA.

The next part of this article highlights the fact that WADA can intervene in matters, where it appears that an unfairness would accrue to an athlete if an MRL were not attached to a non-threshold substance. The timeliness of this intervention may still mean that an athlete needlessly suffers reputational and financial damage.

4 Case study: Brenton Rickard and Furosemide

The case of Australian swimmer Brenton Rickard further highlights the tensions involved when the increased sophistication of anti-doping testing and procedures can detect minute quantities of a prohibited substance. Rickard was an elite Australian swimmer who competed in individual breaststroke events (50 m, 100 m, 200 m) and the 4 × 100 m medley relay. He is a former world-record holder in the 100m breaststroke, and has won individual and medley gold medals at World Championship level, and silver medals at the 2008 Beijing Olympic Games. At the 2012 London Olympic Games, Rickard competed as a heat swimmer in the 4 × 100 m medley relay. In the Olympic final of this event (which Rickard did not swim in), the Australian medley team won a bronze medal. Rickard retired from competitive swimming in 2013.

In September 2020, Rickard was informed that a sample he had provided at the 2012 Olympic Games had been re-analyzed and returned a positive result. The sample contained a minute quantity of the prohibited substance furosemide (6 ng/ml). Furosemide is a diuretic and masking agent and is classified as a 'specified substance' that is prohibited at all times (in- and out-of-competition). At the time that Rickard was notified of this AAF, furosemide was a non-threshold substance, meaning that an ADRV would occur if *any* quantity of the substance was found in an athlete's sample. The fact that this sample was tested in 2012 without returning a positive result, and again in 2020 with a different result, speaks to the increased ability of doping control testing procedures to detect increasingly smaller quantities of a prohibited substance in a sample. This phenomenon is well known by athletes and enforcement bodies alike, and represents a deterrent to athletes who may be able to 'cheat' a doping test in the present, but may subsequently be caught by reanalysis of samples at a later date (up to 10 years later).[108]

[105] Rbb24 (2021), at time 44:50.

[106] Rbb24 (2021), at time 40:31.

[107] World Anti-Doping Agency, 'WADA statement on German broadcaster ARD documentary' (Media Release, 16 July 2021), https://www.wada-ama.org/en/news/wada-statement-german-broadcaster-ard-documentary.

[108] Kolliari-Turner et al. (2021).

On the basis of this AAF from the retested sample, the International Olympic Committee instigated proceedings against Rickard in the Court of Arbitration for Sport in November 2020. This decision was an interesting contrast to the position taken by the IOC in relation to clenbuterol found in retested 2008 Beijing athlete samples. According to WADA, the IOC Re-Analysis Program found, 'a few cases of low levels of clenbuterol, from a number of countries and sports'.[109] These athletes were not subject to anti-doping disciplinary proceedings, on the basis that it would be unfair to ask an athlete to prove that their positive result was the result of meat contamination, eight years after the fact.

In a publicized email that Rickard sent to his relay teammates before his CAS hearing, Rickard explained that he had taken over-the-counter medications in the days before he competed at the London Olympic Games. As diuretics have been known to contaminate over-the-counter medications, it was Rickard's expressed belief that this was the only plausible way in which the furosemide could have entered his system.

Before the CAS hearing between the IOC and Rickard had been finalized, the IOC announced in August 2021 that it was withdrawing the doping violation charges against Rickard, following an anticipated rule change related to a newly introduced DL for some masking agents and diuretics. Effective from 1 January 2022, *WADA Technical Document TD2022MRPL* introduced an MRL for six diuretics of 20ng/ml. Furosemide was one of these six listed diuretics. The rationale for this change was included in WADA Technical Letter TL24:

> At estimated urinary concentrations of 20 ng/mL or less, a diuretic would not be effective to mask the presence of any other Prohibited Substances that may be present in the Sample. Therefore, the new Minimum Reporting Level (MRL) for the six (6) diuretics identified above, set at 20 ng/mL, will minimize the risk of sanctioning Athletes who test positive due to the use of contaminated medications, without undermining the fight for clean sport.[110]

This outcome meant that as Rickard had a concentration of 6 ng/ml of furosemide in his sample, an adverse analytical finding would not be reported. It is interesting to note that in 2012 at the time that Rickard provided his original urine sample, WADA-accredited laboratories were required to be able to detect the presence of diuretics at a level of 250ng/ml and above. The concentration in Rickard's sample fell well below the required testing performance of laboratories at that time.

Had Rickard's case proceeded to final decision in the CAS (without a change in the MRL for furosemide), it is highly likely that he would have been sanctioned for an anti-doping rule violation. Pursuant to Article 2 of the *IOC Anti-Doping Rules 2012*, Rickard had the presence of a prohibited substance (furosemide) in his sample. This is a strict liability violation, so it does not matter that Rickard may have innocently or inadvertently consumed the diuretic in order for the violation to occur. Rickard would then have been sanctioned pursuant to Article 8.1 of the *IOC Anti-Doping Rules London 2012*, with the effect that his bronze medal (and any other prizes) would be forfeited. Unfortunately, this sanction would also extend to all other members of the relay team that Rickard was part of. Article 9 of the *IOC Anti-doping Rules* states:

> In sports which are not Team Sports but where awards are given to teams, if one or more team members have committed an anti-doping rule violation during the Period of the London Olympic Games, the team may be subject to Disqualification, and/or other disciplinary action as provided in the applicable rules of the relevant *International Federation*.

The Fédération Internationale de Natation (FINA) is the relevant International Federation for the purpose of this Article. According to the *FINA Doping Control Rules*, Rule DC 11.2:

> Where any anti-doping rule violation has been committed in relation to an Event by a member of a relay in swimming, or team in open water swimming, or a duet or team in artistic swimming or diving, the relay, duet or team shall be Disqualified from the Event in connection with the anti-doping rule violation, with all resulting Consequences including forfeiture of any medals, points and prizes.

What is evident, is that without a change to the relevant Technical Documents and Letters that inserted an MRL for furosemide, Rickard and his teammates were proverbial 'sitting ducks'. Despite the fact that a rule change was made, leading to the IOC withdrawing its case at the CAS, Rickard cannot be said to have 'won' or 'succeeded' throughout the process. He had the threat of sanction weighing on him for a period of 19 months. He had already spent approximately $50,000 on legal fees. He was, in effect, forced to resign from a role working with the Australian Swimmers Association, and his future career prospects in the sporting domain have been affected. This again begs the question as to whether Rickard's case study is an unfortunate unique case, or whether it exposes systematic flaws in the identification and functioning of DLs and MRLs, or the way that

[109] World Anti-Doping Agency, 'WADA Statement on ARD Documentary' (Media Release, 2 April 2017), < https://www.sportsintegrityinitiative.com/wada-statement-ard-documentary/>.

[110] *Technical Letter 24* v 1.0, p. 1.

they are being monitored and managed as part of the world anti-doping program.

5 Are threshold levels working as intended?

The presence of the WADA Contaminants working group is evidence that WADA is taking the issue of inadvertent doping seriously. Where small quantities of a prohibited substance are found in an athlete's body that are neither performance enhancing nor injurious to health, it becomes obvious to see how an unfairness to athletes may result from the strict liability of anti-doping rule violations in the *Code*. Identification and implementation of DLs for threshold substances and MRLs for non-threshold substances are an important response to this potential unfairness.

Lack of research around the communicability of certain prohibited substances, degrees of contamination in pharmaceuticals/supplements, and knowledge regarding the level at which a prohibited substance may become performance enhancing, still represents a broader problem for the World Anti-Doping Program. Unfortunately, this problem is often transferred to the athlete, who can have the burden of showing that an ADRV was non-intentional and occurred with no (or no significant) fault or negligence. To avoid sanction entirely, the athlete must prove the source of the prohibited substance on the balance of probabilities. Attempting to do this is often an unpredictable gamble for the athlete, especially where the prohibited substance is easily transmittable, and the pharmacokinetic evidence is equivocal.

Solutions to some of the problems surrounding threshold limits are apparent, but they are expensive and require additional research into prohibited substances. As an initial goal, the WADA should proactively and prospectively assess *every* prohibited substance on the prohibited list, to see if they should be subject to a DL or an MRL. Where a threshold should be implemented, its quantitative level should be set using expert advice from the WADA Contaminants Working Group. Technical Documents relating to Decision Limits and Minimum Reporting Levels would then need to be appropriately updated, with an ongoing commitment to update these documents on (at least) an annual basis. The WADA Contaminants Group's Terms of Reference suggests that this work is ongoing. In the meantime, WADA (and other enforcement bodies) must then be careful about prosecuting cases involving prohibited substances at a low quantity, where it remains possible that a DL or an MRL may be attached to that substance in the short-medium term.

In the short-term future, doping cases will arise that expose potential gaps in the operation of DLs and MRLs. Before prosecuting these types of cases, there must be better communication between national anti-doping organizations and the WADA about whether a prosecution should initially proceed. It would not be beneficial for national anti-doping bodies to make unilateral decisions against prosecution, where there is a prima-facie anti-doping rule violation (for obvious reasons). The point made is that if there is a prima-facie anti-doping rule violation that has occurred, but it involves a prohibited substance that may require a threshold limit to be introduced or amended, the prosecution should not commence until these decisions have been made. A potential delay in prosecution need not cause harm to the athlete, if they are fully informed about their adverse analytical finding, the need for further research/testing of the substance, and the possibility of prosecution in the future, pending the outcome of further research/testing.

The benefit of introducing DLs or MRLs to additional prohibited substances can be done in a way that does not undermine the fight against doping in sport. The cynic may suggest that the moment a threshold value is attached to a prohibited substance, athletes will micro-dope in a way that produces performance gain, without crossing the threshold concentration of the substance in a sample. This is possible, but the reality of such a situation can be mitigated through sensible results management procedures. Laboratories have always had the ability to report an athlete's sample as an *atypical finding*. An atypical finding is defined in the *Code* to mean:

> A report from a WADA-accredited laboratory or other WADA-approved laboratory which requires further investigation as provided by the International Standard for Laboratories or related Technical Documents prior to the determination of an Adverse Analytical Finding.[111]

An athlete who has a prohibited substance in their sample below a DL or MRL could be issued an atypical finding report. This allows an anti-doping organization to conduct further investigations, and to determine whether prosecution due to the presence of a prohibited substance in a sample, at a very low concentration, is in the best interests of the anti-doping organization, the athlete and the world anti-doping program collectively. Importantly, it does not prevent an anti-doping organization from continuing to investigate other non-analytical ADRVs, for instance: 'use' of a prohibited substance under article 2.2 of the *Code.* An athlete who receives an atypical finding report could be the subject of targeted anti-doping testing, consistent with the *International Standard for Testing and Investigations* and informed by the non-mandatory *2021 Guidelines for Implementing an Effective Testing Program.*[112] This would be an appropriate

[111] *Code* (2021), Appendix 1.

[112] The International Standard for Testing and Investigations (2021) can be found at: https://www.wada-ama.org/en/resources/world-anti-

and proportionate response to any concerns about the possibility of micro-doping.

Shayna Jack's case is an example of how an introduced MRL for the prohibited substance Ligandrol could have produced a more equitable outcome. If a MRL for Ligandrol was set that collectively acknowledged the communicability of the substance, the level at which it may become performance enhancing and the level consistent with inadvertent doping, then it is argued that a better balance is met between athlete rights and the fight for clean sport.[113] If Jack had a level of Ligandrol in her system that was greater than a set MRL, then it becomes more understandable why she might be expected to defend herself at anti-doping enforcement hearings, including the CAS. If Jack had a level of Ligandrol below the MRL, an atypical finding could be made by a laboratory, with further investigations to follow. Jack would be notified of the atypical finding, and may begin to collect evidence as to the possible source of the contamination. Whilst those investigations are ongoing, Jack would be subject to targeted anti-doping testing, to rule out any systematic micro-doping or ongoing expose to the prohibited substance. The atypical finding would always be present on Jack's record and would be taken into account if she were to test positive to a prohibited substance in the future.

The Brenton Rickard case is a good example of an anti-doping prosecution that should not have commenced. When Rickard's 2012 sample was retested and returned a positive finding for the diuretic furosemide at such low levels, initial alarm bells should have sounded for both WADA and the IOC (as the relevant enforcement body in the particular case). Article 14 of the *Code* has long provided that when a notice containing an AAF or an *atypical finding* is sent to an athlete, the athlete's national anti-doping organization, International Federation, and the WADA are all notified of this result.[114] At this point, a dialogue between WADA and the IOC should have occurred, as to whether prosecution of the ADRV should occur. That dialogue did end up happening, almost a year after Rickard was first informed of his AAF in 2020, on the basis of an anticipated addition of an MRL to the diuretic furosemide. At that point in time, Rickard had already suffered reputational damage, and incurred significant legal expenses contesting the alleged ADRV in the CAS. To make things worse, as the CAS did not make a final determination in the matter, Rickard was unable to recover any costs from the IOC.

6 Conclusion

For a substance to be included on the *Prohibited List*, it must satisfy two of the following three criteria: it has the potential to enhance performance, it poses a potential risk to an athlete's health, or its use violates the spirit of sport.[115] When an athlete has a very low level of a prohibited substance detected in their system that is neither performance enhancing nor injurious to health, and is consistent with inadvertent doping, then it is unfair to that athlete to serve a period of ineligibility of two or four years because they cannot prove the source of the prohibited substance.

This article has considered the role that thresholds for prohibited substances in the form of DLs and MRLs have historically played. The clear argument throughout, highlighted by two recent Australian case studies, is that more prohibited substances on the Prohibited List should be subject to threshold levels. This article does not contend that every substance on the *Prohibited List* should have an MRL, but there is clear justification for expansion; particularly in a context where the science surrounding the long-term health effects, the performance-enhancing effects and the communicability of numerous prohibited substances is uncertain. The fight for clean sport may require strict liability with respect to anti-doping rule violations. A more balanced and nuanced fight for clean sport, offsets the potential harshness of strict liability through the implementation of DLs and MRLs for a greater number of prohibited substances.

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Conflict of interest The authors declare that they have no conflict of interest.

Footnote 112 (continued)

doping-program/international-standard-testing-and-investigations-isti. For the *2021 Guidelines for Implementing an Effective Testing Program*, Chapter 7 is focussed on target testing for athletes.

[113] It is acknowledged that further difficulties emerge in measuring the concentration of a prohibited substance, if the only thing remaining in the sample is a metabolite of the substance. This does not change the argument that an atypical finding would be the appropriate first response in such a situation.

[114] *Code* (2021), art 14.1.2.

[115] *Code* (2021), art 4.3.1.

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Legislation, Codes and International Standards

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Australia *Poisons Standard February 2022* (Cth)

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World Anti-Doping Code (2003, 2009, 2015, 2021)

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