

WADA Technical Document for Sport Specific Analysis - TD2014SSA

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1. Introduction

As part of WADA's move towards ensuring Anti-Doping Organizations (ADOs) implement more intelligent and effective anti-doping programs, Article 5.4.1 of the 2015 World Anti-Doping Code (WADC2015) states – "WADA, in consultation with International Federations and other Anti-Doping Organizations, will adopt a Technical Document under the International Standard for Testing and Investigations (ISTI) that establishes by means of a risk assessment which Prohibited Substances and/or Prohibited Methods are most likely to be abused in particular sports and sports disciplines."

This Technical Document for Sport Specific Analysis (TDSSA) is intended to ensure that the *Prohibited Substances* within the scope of the TDSSA that are deemed to be at risk of abuse in certain sports/disciplines are subject to an appropriate and consistent level of analysis by all *ADOs* that conduct *Testing* in those sports/disciplines. Compliance with the TDSSA is mandatory under the WADC2015.

The development of the TDSSA is based on a scientific approach linking physiological and non-physiological demand of *Athlete* performance with the potential ergogenic benefit of those *Prohibited Substances*. The TDSSA will complement other anti-doping tools and programs such as the *Athlete Biological Passport (ABP)*, intelligence gathering and investigations.

A Minimum Level of Analysis (MLA) is specified for the *Prohibited Substances* within the scope of the TDSSA for each sport/discipline, expressed as a percentage of the total number of eligible Tests and based on a Physiological Risk Assessment of that sport or discipline. The full MLA percentage list by sport/discipline is provided in Appendix 1 and 2 of this Technical Document.

The MLA percentage applies to *Testing* conducted by all *ADOs* on *International-Level Athletes* and *National-Level Athletes* as defined by the applicable *ADO*.

ADOs are encouraged to take advantage of Article 6.4.1 of the WADC2015, which provides for *ADOs* to request that <u>Laboratories</u> analyze their *Samples* using more extensive menus than those prescribed in this Technical Document.

The full *Prohibited List* remains applicable to all sports, including sports that are not covered by the TDSSA and/or for which the MLA is zero. Any *ADO* may, at its own discretion, request a *WADA* accredited laboratory to analyze any *Sample* for the *Prohibited Substances* within the scope of the TDSSA at any time.

WADA accredited laboratories under Article 6.4.3 of the WADC2015 may also, at their own initiative and expense, analyze Samples for Prohibited Substances and/or Prohibited Methods not included in the Sample analysis menu described in the TDSSA or specified by the <u>Testing</u> Authority (TA).

In addition to the mandatory provisions of this Technical Document which include Appendices 1 and 2, WADA has developed a series of supporting documents intended to assist with the implementation and application of the TDSSA. These resources are included herein as Supporting Documents A, B and C but are not to be considered appendices of the TDSSA itself as these will be amended from time to time to reflect the ongoing needs of stakeholders and evolving best practice.

Defined terms in the *Code, International Standards* and the TDSSA can be found in Article 10 of the TDSSA.

2. Objectives of the TDSSA

- 2.1. To protect clean *Athletes* by establishing MLAs for those *Prohibited Substances* within the scope of the TDSSA that are at risk of abuse in particular sports or disciplines.
- 2.2. To enhance the effectiveness of anti-doping programs through a quality-focused approach to Test distribution planning.
- 2.3 To create accountability for stakeholders including International Federations (IFs), National Anti-Doping Organizations (NADOs), Major Event Organizations (MEOs) and other <u>TAs</u> that conduct Testing on such sports and disciplines by implementing the required MLAs.
- 2.4 To maintain and build <u>Laboratory</u> capacity and proficiency for the detection of those *Prohibited Substances* within the scope of the TDSSA.

3. Scope

3.1. Level of Athlete

The requirements of the TDSSA are mandatory for *International-Level Athletes* and *National-Level Athletes* (as defined by IFs and *NADOs*, respectively). *ADOs* may also apply the TDSSA to other *Athletes* within their jurisdiction. For the purpose of meeting the MLAs, only analyses conducted on *International-Level Athletes* and *National-Level Athletes* will be used to assess an *ADO's* compliance with the TDSSA. All *Athletes* that compete in Major Events under the jurisdiction of a *MEO* will, for the purpose of the TDSSA, be presumed to be *International-Level Athletes* or *National-Level Athletes*.

3.2. Prohibited Substances on the TDSSA

From the *Prohibited List*, the *Prohibited Substances* that are within the current scope of the TDSSA are:

- Erythropoiesis Stimulating Agents (ESAs). Section S2.1
- Growth Hormone (GH). Section S2.5

• Growth Hormone Releasing Factors (GHRFs) including Growth Hormone Releasing Hormone (GHRH) and its analogues, Growth Hormone Secretagogues (GHS) and Growth Hormone Peptides (GHRPs). Section S2.5

The *Prohibited Substances* within the scope of the TDSSA are not part of a routine standard urine analysis and require specialized analysis methods.

Information and guidance on those *Prohibited Substances* is provided in Supporting Document B.

The TDSSA does not mandate the use of the *ABP*. However, sports/disciplines for which the MLA for ESAs is 10% are encouraged to consider the benefits of implementing the *ABP* haematological module.

Those sports or disciplines for which the MLA for ESAs is 15% or greater are **strongly recommended** to implement the *ABP* haematological module in the relevant discipline(s) in order to enhance the quality of their anti-doping program.

Implementation of the *ABP* haematological module also enables *ADOs* to seek a reduction in the MLA percentage for ESAs, if they meet the criteria outlined in Article 6 of the TDSSA.

While the TDSSA does not require a MLA for Haemoglobin Based Oxygen Carriers (HBOCs) and Homologous Blood Transfusion (HBT), analysis for HBOCs and HBT should be part of a *Target Testing* strategy based on intelligence (*e.g.* as provided by the *ABP* haematological module or other sources of intelligence).

The TDSSA currently does not require a MLA for Insulins due to limited <u>Laboratory</u> analytical capacity. Therefore, the analysis of Insulins should be part of a *Target Testing* strategy based on intelligence. Insulins may be added to the TDSSA in the future as <u>Laboratory</u> analytical capacity improves.

4. MLA for Sports and Disciplines

Consistent with Article 5.4.1 of the WADC2015, WADA has consulted with IFs and other ADOs in the development of the TDSSA.

MLAs for sports/disciplines are located at:

- **Appendix 1** Sports and Disciplines of Olympic, IOC Recognized and Non-Recognized International Federations¹ and Minimum Levels of Analysis (listed in alphabetical order)
- **Appendix 2** Sports and Disciplines for *Athletes* with an Impairment and Minimum Levels of Analysis (listed in alphabetical order)

5. Test Distribution Planning and MLA Percentages

5.1. <u>Test Distribution Plan</u> (<u>TDP</u>)

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¹ Includes only those non-IOC recognized sports that are members of the Alliance of Independent Members of SportAccord TD2014SSA – Version 2.2 – 15 November 2014 Page 3 of 35

In accordance with Article 4.2 of the *International Standard* for *Testing* and Investigations (ISTI), each *ADO* must undertake in good faith a Risk Assessment as part of the development of an effective <u>TDP</u> under its jurisdiction.

The TDSSA is one important part of the overall <u>TDP</u> process. Once a <u>TDP</u> is developed, each *ADO* will be responsible for managing the implementation of the TDSSA throughout their *Testing* year by applying the required MLAs in a targeted manner to defined *Athletes*.

5.2. Applying MLAs to the <u>TDP</u>

Once an *ADO* has conducted the required Risk Assessment and assigned Tests to a sport or discipline within its <u>TDP</u>, each *ADO* shall apply the prescribed MLA to the number of Tests allocated to each sport or discipline to determine the number of analyses required for each *Prohibited Substance* category as prescribed in the TDSSA.

One Test includes any number of *Samples* that may be collected from one *Athlete* during a single <u>Sample Collection Session</u>. For example, a <u>Sample Collection Session</u> in which one urine <u>Sample</u> and two blood <u>Samples</u> are collected will count as one Test.

As a further example in applying the MLA to a <u>TDP</u>, if an *ADO's* <u>TDP</u> for a sport/discipline consists of 100 Tests and its MLAs are 60% for ESAs, and 10% for GH/GHRFs, then the *ADO* should distribute these analyses as follows:

- 60% ESA analyses to be conducted in either urine or blood
- 10% GH/GHRFs analyses in blood for GH or in either urine or blood for GHRFs

ADOs can request multiple analyses on Samples collected during the same Sample Collection Session. In the example above, the absolute minimum number of <u>Sample Collection Sessions</u> could be 60. This is on the basis that the required number of GH/GHRF analyses are performed on those Athletes who are also being tested for ESAs.

The remaining 40 Tests from the 100 Tests would then be subject to either the standard routine urine analysis or a greater level of analysis, which *ADO*s are encouraged to do.

Whilst the MLAs are mandatory overall, selection of the *Athletes* to be tested, selection of the matrices collected (*i.e.* urine or blood) and the timing of those Tests remain at the discretion of the *ADO*.

Achieving the MLAs for the applicable sports or disciplines should be based on quality of *Testing*, and not simply reaching a required number of Tests. Thus, decisions should be based on intelligence where possible and may include *ABP* information, whereabouts, timing of competition periods, and any other information that may affect the pattern and the timing of *Use* of the *Prohibited Substances* within the scope of the TDSSA. The aim is to test the right *Athletes* for the right *Prohibited Substance(s)* at the right time.

As part of WADA's development and monitoring of ADOs' anti-doping programs, WADA will monitor each ADO's implementation of the TDSSA through ADAMS² and will review through a wider assessment of an ADO's compliance with the ISTI how Tests are being applied, on which Athletes and at what time.

Further guidance on the implementation of the TDSSA within a <u>TDP</u> can be found in the *WADA* "*Guidelines for Implementing an Effective Testing Program"* and in the Frequently Asked Questions (FAQs) located in Supporting Document C.

5.3. Sports/Disciplines without defined MLAs in the TDSSA

Those sports or disciplines that are determined to be at minimal physiological risk to the abuse of the *Prohibited Substances* within the scope of the TDSSA and do not have a MLA, shall be subject to *In-Competition and Out-of-Competition* routine standard urine analysis menus.

However, a sport or discipline may be tested at any time by any *ADO* for those *Prohibited Substances* within the scope of the TDSSA and at a level greater than listed.

6. Seeking a reduction in the MLAs

Article 6.4.2 of the WADC2015 affords *ADOs* the opportunity to request that <u>Laboratories</u> analyze *Samples* with less extensive menus than those prescribed by the TDSSA. Such requests must satisfy *WADA* that "because of the particular circumstances of their country or sport (...) less extensive analysis would be appropriate". Article 4.7.2 of the *International Standard* for *Testing* and Investigations (ISTI) goes further in declaring that *WADA* may approve reductions only when it is satisfied that such reductions "will lead to the most intelligent, effective and efficient use of available Testing resources".

Compliance with the TDSSA alone is not sufficient to demonstrate intelligent, effective and efficient use of available resources. Consequently, the implementation of other 'intelligent *Testing'* strategies will be required before a reduction in MLAs can be considered and approved.

Specifically, WADA shall consider the following criteria when evaluating possible reductions:

6.1 Implementation of the haematological module of the *ABP* (applies to the MLA for ESAs only).

To be eligible for a reduction based on the adoption of the haematological module of the *ABP*, the *ADO* must be able to demonstrate that:

- 6.1.1. Its ABP program has been operational for not less than six months;
- 6.1.2. Its *ABP* program is compliant with the *WADA ABP* Guidelines and relevant Technical Documents, including:

² WADA may require those ADOs that are not currently *ADAMS* users to provide additional reports to validate their compliance with the TDSSA from time to time.

³ To be published in October 2014. TD2014SSA – Version 2.2 – 15 November 2014

The implementation of a real-time *Target Testing* process that acts upon the recommendations of an *Athlete* Passport Management Unit (APMU) or other expert group with reference to ESAs;

- 6.1.3. All relevant *ABP* data is available in *ADAMS* or another system approved by *WADA* to permit oversight by *WADA*;
- 6.1.4 The *ABP* pool includes the majority of relevant *Athletes* from whom an appropriate number of *ABP Samples* have been collected and analyzed annually as recommended by the *ABP* Guidelines, an <u>APMU</u> or other expert group.

The magnitude of any reduction will be discussed between *WADA* and the *ADO* taking into account all the circumstances including the level of ESA testing conducted before the implementation of the TDSSA.

WADA may approve a reduction of up to 50% of the MLA for ESAs based on its decision as to whether the required criteria have been met.

6.2. Particular Circumstances

An application for a reduction in MLA due to particular circumstances may only be made for the *Prohibited Substances* within the scope of the TDSSA. Such particular circumstances must be clearly outlined and supported with relevant documentation.

The burden is therefore on the *ADO* to prove through its application that a reduction in MLA for a sport or discipline will lead to the most intelligent, effective and efficient use of available *Testing* resources.

6.3. Application

The process, template application form and the level of information required to support an application is provided in Supporting Document A.

6.4. Approval Period

An approval for a reduction in MLA will be valid for the duration of the period approved by WADA as long as any specific conditions are continually adhered to by the ADO. WADA may review its approval for reduction of an ADO's MLA at any time.

6.4.1 ABP Haematological Module

WADA's approval for a reduction of an ADO's MLA for ESAs based on the implementation of an effective ABP haematological module will remain valid as long as the ADO continues to meet any requirements set by WADA as part of the original approval. Such approval will roll over year to year subject to any review WADA may wish to conduct. In such situations ADOs do not need to reapply for approval unless circumstances associated with the original approval change.

7. Documentation

ADO's shall provide the following information to ensure that WADA can monitor and evaluate an ADO's implementation of the TDSSA accurately:

7.1. Sport and Discipline

To ensure accurate recording of *Sample* analysis by the <u>Laboratories</u> and reporting of statistics in *ADAMS*, <u>Sample Collection Authorities</u> and their <u>Doping Control Officers</u> must ensure that the correct sport **and discipline** for the *Athlete* is recorded at a minimum on the <u>Laboratory</u> copy of the <u>Doping Control</u> Form (DCF).

7.2. Type of Analysis for each *Sample*

The request for analysis of the *Prohibited Substances* within the scope of the TDSSA shall be provided to the <u>Laboratory</u> for each *Sample* to ensure the <u>Laboratory</u> conducts the correct analyses and accurately reports the results in *ADAMS*. *WADA* will use *ADAMS* to assist with the monitoring and evaluation of an *ADO's* compliance with the TDSSA.

The specific type of analysis required for each *Sample* shall be recorded on the chain of custody (or equivalent) documentation shipped with the *Samples* to the <u>Laboratory</u> or by an otherwise effective communication method that has been agreed with the <u>Laboratory</u> responsible for analyzing an *ADO's Samples*.

As per the ISTI the type of analysis requested shall not be recorded on the DCF.

7.3. Level of *Athlete* being Tested

The TDSSA is applicable to *International-Level Athletes* and *National-Level Athletes* as defined by each IF or *NADO*. To assist with the monitoring of an *ADOs'* <u>TDP</u> and compliance with the application of the MLAs to those defined *Athletes*, *ADOs* are required to develop a system to record the level of *Athlete*. This may be on the *Doping Control* Form, or by other means. *ADOs* may be requested to provide such data to *WADA* as part of *WADA's* wider compliance program.

8. Data Analysis and Monitoring

For TDSSA monitoring and compliance purposes *WADA* will assess whether the *ADO* has met the MLAs based on *Doping Control* statistics. This will include, but not be limited to, the following elements:

- Total number of Tests and types of analyses;
- MLA achieved for each *Prohibited Substance* category within the scope of the TDSSA for each sport/discipline;
- Number of Athletes tested;
- <u>Laboratory</u> capacity

These statistics and any other relevant information will also be used to review and modify the TDSSA over time.

It is expected that *ADOs* will also utilize this data to assist in the review of their <u>TDP</u> and the management of their *Doping Control* programs.

A more comprehensive evaluation of an *ADO's* compliance with the ISTI will include the review of the methods the *ADO* applied to the implementation of the MLAs in the TDSSA, including the selection and timing of Tests and the level of *Athlete* tested. This will be addressed through *WADA's* wider compliance program.

9. Review of TDSSA

As part of an ongoing review process, WADA will monitor the implementation of the TDSSA in consultation with ADOs and WADA accredited laboratories. Revisions to the TDSSA may be issued from time to time based on such consultation or for other reasons at WADA's discretion (e.g. revisions to the Prohibited List or inclusion of an existing Prohibited Substance that is currently not within the scope of the TDSSA). A suitable lead in time will be provided to ADOs in advance of such modifications taking effect.

10. Definitions

10.1 Defined terms from the WADC2015 that are used in the TDSSA

ADAMS: The Anti-Doping Administration and Management System is a Web based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and *WADA* in their anti-doping operations in conjunction with data protection legislation.

Anti-Doping Organization: A Signatory that is responsible for adopting rules for initiating, implementing or enforcing any part of the Doping Control process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other Major Event Organizations that conduct Testing at their Events, WADA, International Federations, and National Anti-Doping Organizations.

Athlete: Any *Person* who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each *National Anti-Doping Organization*). An *Anti-Doping Organization* has discretion to apply anti-doping rules to an *Athlete* who is neither an *International-Level Athlete* nor a *National-Level Athlete*, and thus to bring them within the definition of "Athlete." In relation to *Athletes* who are neither *International-Level* nor *National-Level Athletes*, an *Anti-Doping Organization* may elect to: conduct limited *Testing* or no *Testing* at all; analyze *Samples* for less than the full menu of *Prohibited Substances*; require limited or no whereabouts information; or not require advance *TUEs*. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any *Athlete* over whom an *Anti-Doping Organization* has authority who competes below the international or national level, then the *Consequences* set forth in the *Code* (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all International-Level Athletes and National-Level-Athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond International-Level Athletes or National-Level Athletes to competitors at lower levels of Competition or to individuals who engage in fitness activities but do not compete at all. Thus, a National Anti-Doping Organization could, for example, elect to test recreational-level competitors but not require advance TUEs. But an anti-doping rule violation involving an Adverse Analytical Finding or Tampering, results in all of the Consequences provided for in the Code (with the exception of Article 14.3.2). The decision on whether Consequences apply to recreational-level Athletes who engage in fitness activities but never compete is left to the National Anti-Doping

Organization. In the same manner, a Major Event Organization holding an Event only for masters-level competitors could elect to test the competitors but not analyze Samples for the full menu of Prohibited Substances. Competitors at all levels of Competition should receive the benefit of anti-doping information and education.]

Athlete Biological Passport: The program and methods of gathering and collating data as described in the International Standard for Testing and Investigations and International Standard for Laboratories.

Code: The World Anti-Doping Code.

Doping Control: All steps and processes from Test Distribution Planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, Sample collection and handling, laboratory analysis, TUEs, results management and hearings.

Event: A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).

Event Period: The time between the beginning and end of an *Event*, as established by the ruling body of the *Event*.

In-Competition: Unless provided otherwise in the rules of an International Federation or the ruling body of the *Event* in question, "*In-Competition*" means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.

International-Level Athlete: Athletes who compete in sport at the international level, as defined by each International Federation, consistent with the International Standard for Testing and Investigations.

[Comment: Consistent with the International Standard for Testing and Investigations, the International Federation is free to determine the criteria it will use to classify Athletes as International-Level Athletes, e.g., by ranking, by participation in particular International Events, by type of license, etc.

However, it must publish those criteria in clear and concise form, so that Athletes are able to ascertain quickly and easily when they will become classified as International-Level Athletes. For example, if the criteria include participation in certain International Events, then the International Federation must publish a list of those International Events.]

International Standard: A standard adopted by *WADA* in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standards* shall include any *Technical Documents* issued pursuant to the *International Standard*.

Major Event Organizations: The continental associations of *National Olympic Committees* and other international multisport organizations that function as the ruling body for any continental, regional or other *International Event*.

National Anti-Doping Organization: The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Samples*, the management of test results, and the conduct of hearings at the national level. If this designation has not been made by the competent public authority(ies), the entity shall be the country's *National Olympic Committee* or its designee.

National-Level Athlete: Athletes who compete in sport at the national level, as defined by each National Anti-Doping Organization, consistent with the International Standard for Testing and Investigations.

Out-of-Competition: Any period which is not *In-Competition*.

Prohibited List: The List identifying the Prohibited Substances and Prohibited Methods.

Prohibited Substance: Any substance, or class of substances, so described on the *Prohibited List*.

Regional Anti-Doping Organization: A regional entity designated by member countries to coordinate and manage delegated areas of their national anti-doping programs, which may include the adoption and implementation of anti-doping rules, the planning and collection of *Samples*, the management of results, the review of *TUEs*, the conduct of hearings, and the conduct of educational programs at a regional level.

Sample or Specimen: Any biological material collected for the purposes of *Doping Control*.

Target Testing: Selection of specific *Athletes* for *Testing* based on criteria set forth in the International Standard for Testing and Investigations.

Testing: The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the laboratory.

Use: The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method*.

WADA: The World Anti-Doping Agency.

10.2 Defined Terms from the International Standards that are used in the TDSSA

<u>Athlete Passport Management Unit (APMU):</u> A unit composed of a *Person* or *Persons*, designated by the *Anti-Doping Organization*, responsible for the administrative management of the Passports advising the *Anti-Doping Organization* for intelligent, *Targeted Testing* liaising with the Expert Panel compiling and authorizing an *Athlete Biological Passport* Documentation Package and reporting Adverse Passport Findings.

Doping Control Officer (or DCO): An official who has been trained and authorized by the *Sample* Collection Authority to carry out the responsibilities given to DCOs in the International Standard for Testing and Investigations.

Doping Control Station: The location where the Sample Collection Session will be conducted.

Laboratory(ies): (A) WADA-accredited laboratory(ies) applying test methods and processes to provide evidentiary data for the detection of *Prohibited Substances*, Methods and Markers on the

Prohibited List, and if applicable, quantification of a <u>Threshold Substance</u> in *Samples* of urine and other biological matrices in the context of anti-doping activities.

Major *Event*: A series of individual international *Competitions* conducted together under an international multi-sport organization functioning as a ruling body (e.g., the Olympic Games, Pan American Games) and for which a significant increase of resources and capacity, as determined by *WADA*, is required to conduct *Doping Control* for the *Event*.

Sample Collection Authority: The organization that is responsible for the collection of *Samples* in compliance with the requirements of the International Standard for Testing and Investigations, whether (1) the *Testing* Authority itself; or (2) another organization (for example, a third party contractor) to whom the *Testing* Authority has delegated or subcontracted such responsibility (provided that the *Testing* Authority always remains ultimately responsible under the *Code* for compliance with the requirements of the International Standard for Testing and Investigations relating to collection of *Samples*).

Sample Collection Session: All of the sequential activities that directly involve the *Athlete* from the point that initial contact is made until the *Athlete* leaves the *Doping Control* Station after having provided his/her *Sample(s)*.

<u>Test Distribution Plan</u>: A document written by an *Anti-Doping Organization* that plans *Testing* on *Athletes* over whom it has *Testing* Authority, in accordance with the requirements of Article 4 of the International Standard for Testing and Investigations.

Testing Authority: The organization that has authorized a particular *Sample* collection, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, *WADA*, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization conducting *Testing* pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation).

10.3 Defined terms specific to the TDSSA

Minimum Level of Analysis (MLA): The number of analyses for the Prohibited Substances within the scope of the TDSSA required to be performed by an *ADO* for each sport/discipline, expressed as a percentage of the total eligible Tests in their <u>TDP</u>.

Physiological Risk Assessment: Analysis of the physiological demands of a sport or discipline against the potential performance enhancing benefit of *Prohibited Substances* on the TDSSA.

Risk Assessment: An all-inclusive assessment of risk (as described in the *International Standard* for *Testing* and Investigations) of a sport or discipline in relation to doping that considers a wide range of risk factors in addition to physiological risk. Such factors may include doping history, financial gain, gender, age, status of the sport within a country etc.

Test: Any combination of *Sample*(s) collected (and analyzed) from a single *Athlete* in a single *Sample* Collection Session.

Sports and Disciplines of Olympic, IOC Recognized and Non-IOC Recognized International Federations 4 and Minimum Levels of Analysis

SPORT	DISCIPLINE	ESAs %	GH & GHRFs %
Aikido	Aikido	5	5
Air Sports	All	0	0
American Football	American Football	5	10
Aquatics	Diving	0	5
Aquatics	Swimming Sprint (100 m or less)	10	10
Aquatics	Swimming Long Distance (800 m or greater)	30	5
Aquatics	Swimming Middle Distance (200-400 m)	15	5
Aquatics	Open Water	30	5
Aquatics	Synchronised Swimming	10	5
Aquatics	Water Polo	10	10
Archery	All	0	0
Athletics	Combined Events	15	15
Athletics	Jumps	10	15
Athletics	Long distance (3000 m or greater)	60	5
Athletics	Middle Distance (800-1500 m)	30	10
Athletics	Sprint (400m or less)	10	15
Athletics	Throws	5	15
Automobile Sports	All	5	0
Badminton	Badminton	10	10
Bandy	Bandy	5	10
Baseball	Baseball	5	10
Basketball	Basketball	10	10
Basketball	3 on 3	10	10
Biathlon	Biathlon	60	10
Basque Pelota	Basque Pelota	5	5
Billiards Sports	All	0	0
Bobsleigh	Bobsleigh	5	10
Bobsleigh	Skeleton	0	10
Bodybuilding	Bodybuilding	5	30
Bodybuilding	Fitness	10	30
Boules Sports	All	0	0
Bowling	All	0	0
Boxing	Boxing	15	10
Bridge	Bridge	0	0
Canoe/Kayak	Sprint (200 m)	10	10
Canoe/Kayak	Canoe Slalom	15	10

⁴ Includes only those non-IOC recognized sports that are members of the Alliance of Independent Members of SportAccord TD2014SSA – Version 2.2 – 15 November 2014 Page 12 of 35

SPORT	DISCIPLINE	ESAs %	GH & GHRFs %
Canoe/Kayak	Canoe Polo	5	10
Canoe/Kayak	Middle Distance (500 m)	15	10
Canoe/Kayak	Dragon Boat	10	5
Canoe/Kayak	Freestyle	5	10
Canoe/Kayak	Long Distance (1000 m)	30	5
Canoe/Kayak	Marathon	30	5
Canoe/Kayak	Ocean Racing	15	5
Canoe/Kayak	Wildwater	5	10
Casting	Casting	0	0
Cheer	Cheer	5	5
Chess	Chess	0	0
Cricket	All	5	10
Curling	Curling	0	0
Cycling	вмх	5	10
Cycling	Cyclocross	30	10
Cycling	Indoor Cycling (Artistic, Cycle Ball, Trials)	5	5
Cycling	Mountain Bike	30	10
Cycling	Road	60	10
Cycling	Track Endurance	60	10
Cycling	Track Sprint	10	10
Dance Sport	All	5	5
Darts	Darts	0	0
Dragon Boat	Dragon Boat	10	5
Draughts	Draughts	0	0
Equestrian	Dressage	0	0
Equestrian	Driving	0	0
Equestrian	Eventing	5	5
Equestrian	Endurance	5	5
Equestrian	Jumping	5	5
Equestrian	Reining	0	0
Equestrian	Vaulting	5	5
Fencing	All	5	5
Field Hockey	Field Hockey	10	10
Fistball	Fistball	5	5
Floorball	Floorball	5	5
Flying Disc	Ultimate	5	5
Football	Beach Football	5	5
Football	Football	10	10
Football	Futsal	5	5
Go	Go	0	0
Golf	Golf	5	5
Gymnastics	Artistic	10	10

SPORT	DISCIPLINE	ESAs %	GH & GHRFs %
Gymnastics	Acrobatics	5	10
Gymnastics	Rhythmic	5	5
Gymnastics	Aerobics	10	5
Gymnastics	Trampoline	5	5
Gymnastics	Tumbling	5	5
Handball	Beach	5	5
Handball	Indoor	10	10
Ice Hockey	Ice Hockey	5	10
Icestocksport	Icestocksport Target	0	0
Icestocksport	Icestocksport Distance	0	5
Ju-Jitsu	All	10	10
Judo	Judo	10	10
Karate	Karate	10	10
Kendo	Kendo	5	5
Kickboxing	All	15	10
Korfball	Korfball	10	5
Lacrosse	Lacrosse	10	10
Lifesaving	Beach	10	5
Lifesaving	Pool	10	5
Luge	Luge	0	10
Minigolf	Minigolf	0	0
Modern Pentathlon	Modern Pentathlon	5	5
Motorcycle Racing	All	5	0
Mountaineering and Climbing	All	10	5
Muaythai	Muaythai	15	10
Netball	Netball	10	5
Orienteering	All	15	5
Polo	All	5	5
Powerboating	Aquabike	5	5
Powerboating	Circuit	0	0
Powerboating	Offshore	0	0
Powerlifting	All	5	30
Racquetball	Racquetball	10	5
Roller Sports	Artistic	5	5
Roller Sports	Hockey	5	10
Roller sports	Inline Speed Skating Sprint (1000 m or less)	15	10
Roller Sports	Inline Speed Skating Distance (>1000 m)	30	10
Rowing	Rowing	30	10
Rugby Union	Fifteens	10	10
Rugby Union	Sevens	10	10
Sailing	All	5	5
Sambo	Sambo	10	10

SPORT	DISCIPLINE	ESAs %	GH & GHRFs %
Savate	All	10	10
Sepaktakraw	All	0	0
Shooting	All	0	0
Skating	Figure Skating	10	10
Skating	Short Track (1500 m or less)	15	10
Skating	Short Track (>1500 m)	30	10
Skating	Speed Skating (1500 m or less)	15	10
Skating	Speed Skating (>1500 m)	30	10
Skating	Synchronized Skating	10	5
Ski Mountaineering	Ski Mountaineering	30	5
Skiing	Alpine	15	10
Skiing	Cross-Country	60	10
Skiing	Nordic Combined	30	10
Skiing	Freestyle Skiing	10	5
Skiing	Ski Jumping	0	5
Skiing	Snowboard	10	5
Sleddog	Sleddog	0	0
Soft Tennis	Soft Tennis	5	5
Softball	Softball	5	10
Sport Climbing	Boulder	10	10
Sport Climbing	Lead	10	5
Sport Climbing	Speed	10	5
Sport Fishing	Sport Fishing	0	0
Squash	Squash	10	5
Sumo	Sumo	10	10
Surfing	All	10	5
Table Tennis	Table Tennis	5	5
Taekwondo	Poomsae	5	5
Taekwondo	Sparring	10	10
Tennis	Tennis	10	5
Triathlon	All	60	10
Tug of War	Tug of War	5	10
Underwater Sports	Apnoea	15	5
Underwater Sports	Aquathlon (Underwater Wrestling)	15	10
Underwater Sports	Finswimming Open Water	30	5
Underwater Sports	Finswimming Pool	15	5
Underwater Sports	Free Immersion	15	5
Underwater Sports	Spear Fishing	15	5
Underwater Sports	Target Shooting	0	0
Underwater Sports	UW Hockey	5	5

SPORT	DISCIPLINE	ESAs %	GH & GHRFs %
Underwater Sports	UW Rugby	5	5
Volleyball	Beach	5	5
Volleyball	Volleyball	5	5
Waterskiing	Racing Water Ski	5	5
Waterskiing	Slalom	5	5
Waterskiing	Tricks & Jumps	5	5
Waterskiing	Wakeboard	5	5
Weightlifting	Weightlifting	5	30
Wrestling	All	15	10
Wushu	Sanda	10	10
Wushu	Taolu	5	5

Sports and Disciplines of Athletes with an Impairment and Minimum Levels of Analysis

SPORTS	DISCIPLINE	ESAs %	GH & GHRFs %
Aquatics	IPC Swimming (100 m or less)	5	10
Aquatics	IPC Swimming Middle Distance (200-400 m)	10	5
Aquatics	IPC Swimming Long Distance (800 m or greater)	30	5
Archery	Para-Archery	0	0
Athletics	IPC Combined Events	15	10
Athletics	IPC Jumps	5	10
Athletics	IPC Sprint (400 m or less)	5	10
Athletics	IPC Throws	5	10
Athletics	IPC Middle Distance (800-1500 m)	30	5
Athletics	IPC Long Distance (3000 m or greater)	30	5
Badminton	Para-Badminton	5	5
Basketball	Wheelchair Basketball	5	5
Biathlon	IPC Biathlon	30	10
Bobsleigh	Para-Bobsleigh	5	5
Boccia	Para-Boccia	0	0
Canoe/Kayak	Para-Canoe Sprint	10	10
Curling	Wheelchair Curling	0	0
Cycling	Para-Cycling Track Sprint	5	5
Cycling	Para-Cycling Road	30	5
Cycling	Para-Cycling Track Endurance	30	5
DanceSport	IPC Wheelchair DanceSport	0	0
Equestrian	Para-Equestrian	0	0
Fencing	Wheelchair Fencing	5	5
Field Hockey	Para-Field Hockey	5	5
Football-5-a-side	Para-Football-5-a-side	5	5
Football-7-a-side	Para-Football-7-a-side	5	5
Goalball	Goalball	5	5
Handball	Para-Handball	5	5
Ice Sledge Hockey	IPC Ice Sledge Hockey	5	5
Judo	Para-Judo	10	10
Luge	Para-Luge	0	5
Powerlifting	IPC Powerlifting	5	30
Rowing	Para-Rowing	30	10
Rugby	Wheelchair Rugby	5	5
Sailing	Para-Sailing	0	0

SPORTS	DISCIPLINE	ESAs %	GH & GHRFs %
Skiing	Para-Snowboard	5	5
Shooting	IPC Shooting	0	0
Skiing	IPC Alpine	10	5
Skiing	IPC Cross-Country Sprint/Short Distance	30	10
Skiing	IPC Cross-Country Middle/Long distance	30	10
Table Tennis	Para-Table Tennis	5	5
Taekwondo	Para-Taekwondo-Kyorugi	10	10
Tennis	Wheelchair Tennis	5	5
Triathlon	Para-Triathlon	30	10
Volleyball	Sitting Volleyball	5	5

Supporting Documents of the TDSSA:

In addition to the mandatory provisions of this Technical Document, *WADA* has developed a series of supporting documents intended to assist with the implementation and application of the TDSSA. These resources are included herein but are not to be considered appendices of the TDSSA itself as these will be amended from time to time to reflect the ongoing needs of stakeholders and evolving best practice.

- a. Applying to WADA for a reduction in the Minimum Levels of Analysis
- b. Information and Guidance on the *Prohibited Substances* within the scope of the TDSSA
- c. Frequently Asked Questions (FAQs) on the TDSSA

Applying to WADA for a reduction in the Minimum Levels of Analysis

In accordance with Article 6 of the TDSSA and in compliance with Article 4.7.2 of *the International Standard* for *Testing* and Investigations, *WADA* may approve reductions of MLAs when it is satisfied that such reductions "will lead to the most intelligent, effective and efficient use of available *Testing* resources" and meet the criteria listed in Article 6 of the TDSSA.

The process for an *ADO* to apply for a possible reduction is as follows:

- 1. Submit an application to WADA (<u>tdssa@wada-ama.org</u>) by completing the application form below⁵.
- 2. This application must include the following:
 - a. Name of *ADO* and name and contact details of the individual(s) responsible for the development and implementation of the *ADO*'s <u>Test Distribution Plan</u>;
 - b. Complete <u>Test Distribution Plan</u> for the previous, current and upcoming year including, but not limited to, all sports and disciplines over which the ADO has jurisdiction for the collection of *Samples* (including those (to be) collected), (planned) analyses, events where *Samples* were/will be collected, and a brief description of the rationale for each;
 - c. ADO's definition of International-Level or National-Level Athlete and the number of Athletes meeting such criteria;
 - d. ADO's anti-doping budget for the previous, current and upcoming (if applicable) year;
 - e. Existing sport specific anti-doping strategies;
 - f. Description of how the *ADO* believes a reduction in the TDSSA can support a more intelligent, effective and efficient use of available *Testing* resources for their country or sport(s)/disciplines;
 - q. Description of intelligent or innovative *Testing* strategies utilized by the ADO;
 - h. Detailed explanation of any other particular circumstances supporting the *ADO'*s request for a reduction in MLAs; and
 - i. All documented evidence that supports a review of the haematological module of the *ABP* where the *ADO* is seeking a reduction in the MLA for ESAs as outlined in Article 6 of the TDSSA.

ADOs may submit an application for a reduction of MLAs for multiple sports or disciplines within the same application.

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⁵ ADOs' applications must be submitted in either English or French. TD2014SSA – Version 2.2 – 15 November 2014

CODE ARTICLE 6.4.2 APPLICATION FOR A REDUCTION IN THE MINIMUM LEVELS OF ANALYSIS

APPLICANT(S) NAME	
Individual(s) responsible for the	
development and implementation of	
the ADO's TDP	
ADO NAME	
CONTACT INFORMATION	
Email	
Phone	
calendar or fiscal year unless there are exceptional	ne. However, applications should normally be made in advance of the all circumstances that justify an application at any other time (reasons to be as WADA has approved a reduction and specified what reduction will be with the TDSSA in full.
DESCRIBE IN DETAIL HOW A PEDILO	TION IN THE MLA(s) ON THE TDSSA CAN SUPPORT A
MORE INTELLIGENT, FEFFCTIVE AN	D EFFICIENT USE OF YOUR AVAILABLE TESTING
	REOUIRED INFORMATION OUTLINED IN 2b) TO 2i)
RESOURCES. PLEASE INCLUDE THE	REQUIRED INFORMATION OUTLINED IN 2b) TO 2i)
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RESOURCES. PLEASE INCLUDE THE	REQUIRED INFORMATION OUTLINED IN 2b) TO 2i)

WADA will consider the application and communicate a decision to the ADO no later than six weeks after the initial application is received.

Information and Guidance for the Prohibited Substances within the scope of the TDSSA

Erythropoiesis Stimulating Agents (ESAs)

ESAs include recombinant erythropoietins and their analogues and mimetics that stimulate erythropoiesis (red blood cell production). ESAs increase net oxygen delivery to muscles by increasing red cell mass and $VO2_{max}$, thereby improving endurance. ESAs are also known to allow *Athletes* to undertake intensive training sessions and be used to support a faster recovery during heavy training phases.

Whilst ESAs are most commonly analyzed in urine, ESAs are detectable in either blood or urine. It must be noted that the detection of continuous erythropoietin receptor activator (CERA) is more sensitive in blood serum than urine and is not always detectable in urine.

One analysis towards the minimum level of analysis (MLA) requirement shall be counted irrespective of whether an ESA analysis takes place on a urine or blood *Sample*.

Human Growth Hormone (GH) and Growth Hormone Releasing Factors (GHRFs)

These two groups of substances have been combined in the TDSSA to recognize the current global *WADA* accredited laboratories' analytical capacity⁶. It is recommended that the majority of the MLA for GH/GHRFs should be conducted for GH since all *WADA* accredited laboratories can analyze for GH but not all currently have the methods to analyze GHRFs.

GH

GH is a hormone normally produced by the pituitary gland of the brain. The metabolic actions of GH also interact with those of Insulin and anabolic steroids promoting enhanced anabolic effects and increased lean muscle mass. Growth hormone also has a strong lipolytic effect (loss of fat) and may improve soft tissue healing and recovery.

Currently, GH can only be detected in blood serum. There are two types of detection methods for GH:

- 1. GH isoforms (direct detection method) and;
- 2. GH biomarkers (indirect detection method).

The GH isoforms test has been implemented in all WADA accredited laboratories.

The GH biomarkers test remains valid, however the component assays were withdrawn from the market and new assays are currently undergoing a revalidation process and will be available in the near future. This test will be initially available to a limited number of accredited <u>Laboratories</u> with a gradual implementation among other WADA <u>Laboratories</u> over time.

⁶ The list of WADA accredited laboratories, the analysis methods they offer and the costs associated for their analytical services will be stored securely in ADAMS for ADOs to access and will be available to ADOs as of 1 January 2015

When the GH biomarkers test becomes available again, *ADOs* should request both types of GH detection methods when analyzing a *Sample* for GH due to the complementary nature of the two methods. The GH isoforms Test detects GH doping up to 24-48 hours after administration. The GH biomarkers Test, which measures changes in concentration levels of two main markers of GH biological action, namely IGF-1 and P-III-NP, may not detect GH in the initial phase of use but does at later times and for a longer period than the GH isoforms Test.

One analysis toward the MLA requirement shall be counted irrespective of the GH detection method applied to a *Sample*.

As outlined in Article 4.7.3 of the ISTI, ADOs shall incorporate into their <u>TDP</u> a strategy for the retention of Samples to enable further analysis of such Samples at a later date. The storage of blood serum Samples (following the analysis with the GH isoforms method) until the <u>Laboratory</u> has the capacity to analyze the Samples using the biomarkers detection method, would be a recommended strategy.

GHRFs

GHRFs are synthetic substances that may have performance enhancing effects by stimulating the endogenous production of GH.

GHRFs can be analyzed in urine or blood serum. *ADO*s should confirm with the applicable <u>Laboratories</u> (who have capacity for this Test) as to which matrix and methods are validated in the Laboratory.

It is recommended that when a blood *Sample* is collected for GH analysis, GHRFs are also analyzed in any urine *Sample* collected during the same *Sample* Collection Session. If both analyses for GH and GHRFs are performed, this will count as two analyses towards the GH/GHRFs MLA requirements. If only GHRFs are analyzed then it will count as one analysis towards the GH/GHRFs MLA requirements.

FREQUENTLY ASKED QUESTIONS (FAQs) ON THE TDSSA7

General

1. What is the TDSSA?

The TDSSA is a tool that is intended to assist *Anti-Doping Organizations (ADOs)* in achieving more intelligent and effective *Testing* programs for sports/disciplines by requiring a <u>minimum level</u> of analysis for *Prohibited Substances* that are not currently part of the standard routine urine analysis menu.

The TDSSA – which is mandated by Article 5.4.1 of the 2015 *World Anti-Doping Code* (WADC2015) which all signatories approved – will further protect the clean *Athletes* by ensuring that the *Prohibited Substances* deemed to be at risk of abuse in certain sports/disciplines are subject to an appropriate and more consistent level of analysis by all *ADOs* that conduct *Testing* on those sports/disciplines.

2. When does the TDSSA become effective?

The TDSSA will come into effect on 1 January 2015.

3. To whom does the TDSSA apply?

The TDSSA applies to all ADOs that authorize the collection of Samples. This includes International Federations (IFs), National Anti-Doping Organizations (NADOs), Regional Anti-Doping Organizations (RADOs) and Major Event Organizations (MEOs).

4. Which Prohibited Substances are within the scope of the TDSSA?

- Erythropoiesis Stimulating Agents (ESAs) (e.g. recombinant erythropoietins and their analogues);
- Human Growth Hormone (GH) and Growth Hormone Releasing Factors (GHRFs) include Growth Hormone Releasing Hormone (GHRH) and its analogues and Growth Hormone Releasing Peptides (GHRPs).

5. What was the process by which the Minimum Levels of Analysis (MLAs) were developed?

A drafting group of experts was appointed by *WADA* to develop the TDSSA with science, laboratory, exercise physiology and anti-doping backgrounds, covering a number of stakeholder groups.

The members of the TDSSA drafting group are:

1. Dr. Peter Harcourt (Chair) - Chair of Medical Committee, FIBA

The FAQs on the TDSSA is a supporting document to assist ADOs with the implementation of the TDSSA. Where the interpretation of any text within the FAQ is in contradiction with the TDSSA, the TDSSA shall prevail.
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- 2. Dr. Richard Budgett Medical and Scientific Director, IOC
- 3. Dr. Stuart Miller Executive Director, Science and Technical, ITF & Member, ASOIF Medical Consultative Group
- 4. Prof. Don McKenzie Exercise Physiologist and Chair of Anti-Doping/Medical Committee, ICF
- 5. Dr. Toni Pascual Barcelona Laboratory and Chair of IPC Anti-Doping Committee
- 6. Dr. Matt Fedoruk Science Director, USADA
- 7. Rune Andersen Advisor, Anti-Doping Norway

The group undertook an extensive consultation process with the International Federations (IFs) of Olympic, IOC Recognized and Non-IOC Recognized sports and sports disciplines, and evaluated the *Prohibited Substances* within the scope of the TDSSA from a physiological risk and ergogenic benefit perspective. *WADA* also consulted with other *ADOs* including *National Anti-Doping Organizations (NADOs)* and *Major Event Organizations (MEOs)*.

The draft MLA requirements contained in Appendix 1 and 2 of the TDSSA are listed as a percentage (%) of total eligible Tests in each specific analysis category. These MLAs are based on a Physiological Risk Assessment that considered physiological demand and non-physiological factors in each sport/discipline, as well as WADA accredited laboratory analytical capacity for the Prohibited Substances, analyses conducted historically by ADOs and a relative physiological and non-physiological comparison of sports/disciplines within similar categories.

The input of the *ADOs*, particularly IFs who have direct expertise in their sport, was critical in determining the assessments described above.

6. Were factors other than physiological and non-physiological demand – such as financial gain, sport culture in a country, country performance, intelligence or gender – considered when establishing the MLAs?

No, these factors should be considered by each *ADO* as part of the wider Risk Assessment that *ADO*s must conduct in accordance with Article 4.2 of the *International Standard* for *Testing* and Investigations (ISTI), which is an important step in the development of their <u>Test Distribution Plan</u> (TDP).

7. <u>Is there a guideline to assist ADOs in conducting a Risk Assessment and to optimize the effectiveness of their testing programs?</u>

WADA has developed a new WADA Guideline titled "Guidelines for Implementing an Effective Testing Program" to assist ADOs with conducting the overall Risk Assessment and <u>TDP</u> elements of their program. The Guideline will focus on the development of 'smart' Testing programs based on a more qualitative approach rather than strictly a quantitative one.

8. Will WADA be monitoring ADO compliance with the TDSSA in 2015?

It is anticipated that full application of the MLAs may take some time for all *ADOs* to implement into their *Testing* programs.

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To be published in October 2014.
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Therefore the focus of the TDSSA in 2015 will be its implementation by *ADOs* rather than solely compliance. Consultation with *ADOs* will be an integral part of the implementation phase to support the ongoing development of the TDSSA.

WADA encourages all ADOs to try and meet the MLAs in 2015 so that an effective review can take place.

9. <u>Will the TDSSA form part of the overall Code compliance process? If so, how will</u> compliance with the TDSSA be monitored?

Yes. However, as outlined above, 2015 will be a year of adaptive implementation of the TDSSA. Part of this process will include assisting *ADOs* with the implementation of the TDSSA, consultation and assessment of feedback.

The TDSSA will be monitored and evaluated through *ADAMS* and *WADA's* review of *ADOS'* implementation of their *Testing* programs.

10. How should the cost implications of the TDSSA be managed?

The TDSSA exemplifies the rationale for establishing a minimum level of analysis based on an objective, quality-based *Testing* approach.

For those *ADOs* whose <u>TDPs</u> already exceed the MLAs, there will be no impact on their programs and they should continue with their current levels of analyses and not reduce them.

Those *ADOs* that are not currently conducting the required MLAs will need to review how they can optimize the use of existing resources within their anti-doping program or seek additional funding from their funding bodies.

Where additional funding is not available or the redistribution of resources/programs within an *ADO* is not possible, a reduction in Test numbers by the *ADO* may occur in order to reach the MLA. However it should not reduce the Test numbers to a level where a program becomes ineffective.

11. What will be the benefits of the TDSSA?

The introduction of the TDSSA will contribute to:

- Increased levels of deterrence from a greater range of sports/disciplines and *Athletes* being tested for *Prohibited Substances* within the scope of the TDSSA
- A possible increase in detection rates for *Prohibited Substances* within the scope of the TDSSA
- An increase in the analytical capacity of <u>Laboratories</u>
- Greater protection of the rights of clean Athletes.

12. What messages can ADOs take to their funding bodies when seeking additional resources to implement the requirements of the TDSSA?

- The TDSSA is a tool that will provide greater protection to the clean *Athletes*.
- Article 23.3 of the WADC2015 (Implementation of Anti-Doping Programs) states:

"Signatories shall devote sufficient resources in order to implement anti-doping programs in all areas that are compliant with the Code and the International Standards".

- The TDSSA is a mandatory level-two document of the WADC2015 that signatories are required to implement.
- The TDSSA will be part of WADA's measurement of ADOs' Code compliance.

Implementing the TDSSA and Test Planning

13. Which Athletes are subject to the TDSSA?

The TDSSA will only apply to *National-Level* and *International-Level Athletes*, as defined by *NADO*s and IFs in their Anti-Doping Rules. *ADO*s may conduct additional analysis on other *Athletes* at any time but such Tests will not be counted towards achieving the required MLAs of the TDSSA.

Further information on the definition of an *Athlete* can be found in the WADC2015 definitions and Article 4.3 of the *ISTI*.

14. Does an Athlete need to know what level of Athlete they are at the time of a Test?

No. The *Testing* Authority who authorized or requested the Test is responsible for putting in place a system to record the level of *Athlete* being Tested; as defined by the IF or *NADO*. This may be on the DCF, or by other means. It should not be the responsibility of the *Athlete* to know what level of *Athlete* they are at the time of a Test.

The level of *Athlete* does not prevent any *Athlete* being tested for all *Prohibited Substances* on the *Prohibited List* at any time.

15. <u>If an Athlete is subject to Testing by multiple ADOs, which ADO receives credit for the MLA?</u>

In some situations an *Athlete* may be subject to *Testing* under the authority of his or her IF, *NADO* or an *MEO*. Any MLA analyses conducted on an *Athlete* will be counted towards meeting the MLA requirements based on who the *Testing* Authority was that requested the Test.

16. <u>How should specific analysis of tests collected under the TDSSA be allocated between Athletes?</u>

ADOs should make this decision as part of their <u>TDP</u> management and through utilizing available intelligence and identified risk factors particular to each sport/discipline and *Athlete's* circumstances that provide a more targeted approach to selection.

17. Should NADOs apply the MLAs in each sport that is listed separately on the TDSSA or only in those sports and disciplines that are part of the NADO's TDP?

The TDSSA is a sport/discipline specific document that relates to *International-Level* and *National-Level Athletes*. *NADO*s must comply on an individual basis with the TDSSA for every sport or discipline within their jurisdiction in which they plan to test as part of their <u>TDP</u>.

18. How should an ADO calculate the MLAs and apply them to its TDP?

A Test shall be the basis of the calculation of the MLA. One Test includes any number of *Samples* that may be collected from one *Athlete* during an individual *Sample* Collection Session.

Once an *ADO* has applied the number of Tests to a sport or discipline following its Risk Assessment, it then applies the MLA percentages to those Tests. Multiple analyses can be conducted on one *Sample*, whether it be blood or urine collected during one <u>Sample Collection Session</u>. The *Athletes* and *Samples* to which those analyses are applied are at the *ADO*'s discretion.

As an example, if an *ADO* plans to conduct 100 Tests in a sport or discipline and the MLAs are 60% for ESAs, and 10% for GH/GHRFs, the *ADO* should distribute these analyses as follows:

- 60 ESA analyses to be conducted in either urine or blood
- 10 GH/GHRFs analyses in blood for GH or in either urine or blood for GHRFs

*ADO*s can request multiple analyses on *Samples* collected during the same <u>Sample Collection</u> <u>Session</u>. In this example the absolute minimum number of <u>Sample Collection Sessions</u> or Tests could be 60. This is on the basis that GH/GHRF analyses are performed on those *Athletes* who are also being tested for ESAs.

The remaining 40 Tests from the 100 Tests would then be subject to either the standard routine urine analysis or a greater level of analysis for the *Prohibited Substances*, within the scope of the TDSSA which *ADO*s are encouraged to do.

The application of these analyses to *Athletes* subject to the TDSSA should be based on intelligence and identified risk factors particular to each *Athletes'* circumstances.

19. What should an ADO do if a sport or discipline which has been allocated a small number of Tests has a MLA that results in the required number of analyses under the TDSSA being less than one?

In this situation, the *ADO* shall conduct a greater level of analysis than the calculation of the TDSSA prescribes, which at a minimum should be one test. As an example, if a sport discipline is required to conduct 0.5 of an ESA analysis because the actual number of Tests is 5 and the ESA MLA is 10%, then the *ADO* will be required to conduct a minimum of 1 ESA Test. In addition, any portion of a Test shall be required to be rounded up to the nearest whole Test for calculation purposes. This situation will also be applicable to a number of *ADO*s who implement small Testing programs for a particular sport or discipline. *WADA* will review this position as part of the TDSSA implementation in 2015 and provide further guidance as required.

20. <u>Are Samples collected as part of a haematological module of the Athlete Biological Passport (ABP) subject to the TDSSA?</u>

No. The ABP haematological module is not directly part of the TDSSA. However, it is an important tool for effective *Testing* in those sports or disciplines that may be at risk to abuse of the *Prohibited Substances* and *Prohibited Methods* that affect the haematological profile of an *Athlete*, such as ESAs.

As outlined in the TDSSA, it is <u>strongly recommended</u> that any sport or discipline with an ESA MLA of 15%, or greater implements the ABP haematological module.

Those sports or disciplines with an ESA MLA of 10% are encouraged to consider the benefits of implementing the ABP haematological module.

WADA will provide the necessary support required to ADOs in establishing ABP programs.

21. When implementing an ESA analysis program that is supported by an ABP haematological model, should any Target Tests be based solely on the review of blood profiles by an Athlete Passport Management Unit (APMU)?

An APMU plays a key role in reviewing blood profiles and guiding the *ADO* when *Target Testing* should be conducted. This is one reason why a reduction in ESA MLAs is available for those *ADOs* that are implementing an effective ABP program. However, there may be times when the *Athlete's* passport does not clearly reflect blood manipulation either because of pathology or micro dosing protocols and therefore the *ADO* should also rely on other intelligence and risk factors to guide them with the targeting for ESAs.

22. <u>Can Samples collected under an ABP haematological module be part of the calculation in reaching the MLAs?</u>

No. Samples collected solely for the purpose of the ABP haematological module will not be part of the evaluation in meeting the MLA and will not be part of the calculation for the required number of analyses under the TDSSA.

However, if A and B blood or urine samples are also collected from the same *Athlete* during the same *Sample* Collection Session and analyzed for *Prohibited Substances* within the scope of the TDSSA along with the haematological parameters for the *ABP* then the analyses of those *Prohibited Substances* within the scope of the TDSSA will count towards meeting the required MLAs.

23. What sport /discipline should be applied to the Doping Control Form (DCF) for *Out-of-Competition Samples* collected from an *Athlete* who competes in a broad range of sport disciplines?

The Athlete's discipline should be recorded as the one that has the highest MLA percentage.

24. <u>If an Athlete competes in more than one discipline (as listed in the TDSSA) at an event, what MLA applies if they are different?</u>

The discipline in which the *Athlete* competed and was selected for *Testing* should be the discipline to which the MLA applies.

25. Is it important that an ADO records the discipline of a sport on the DCF?

Yes. An *ADO*'s DCF must contain the discipline of a sport on the <u>Laboratory</u> copy of the DCF so that the <u>Laboratory</u> can assign a discipline to the sport when reporting the results and type of analysis. If the discipline is not provided, then the analysis statistics by sport and discipline will not be accurate for that *ADO*, which will affect the evaluation of the *ADO*'s implementation of the TDSSA.

26. Is it mandatory that an ADO record the level of Athlete on the Doping Control Form?

No. It is currently not mandatory. However, *ADOs* are required to develop a system to record the level of *Athlete* either on their *Doping Control* Forms or otherwise for the purpose of monitoring their <u>TDP</u> progress and their compliance with the application of the MLAs to those defined *Athletes*. *ADOs* may be requested to provide such data to *WADA* as part of *WADA's* wider compliance program. As part of the further consultation process with *ADOs* on the implementation of the TDSSA, *WADA* will consider how this information can be efficiently recorded and accessed in *ADAMS*.

27. What if a sport does not have a discipline listed in the TDSSA?

Where the sport and discipline are listed the same in the TDSSA (e.g. weightlifting), they should be recorded in *ADAMS* and on the DCF this way.

28. Where a sport has the discipline listed as "All" in the TDSSA, how should the ADO apply the MLAs to the disciplines of that sport and how should the disciplines be listed in ADAMS and on the DCF?

In this case, the *ADO* has the discretion to distribute the MLAs across the disciplines of the sport equally or to those disciplines the ADO identifies as having the higher risk(s) to those *Prohibited Substances* within the scope of the TDSSA. As part of the evaluation of the TDSSA in 2015, *WADA* may decide to list those disciplines individually in the 2016 TDSSA rather than under the "All" category.

For these sports, *ADO*s should list the actual discipline of the sport that is receiving *Testing* on the DCF. For example: Sport = Cricket, Discipline = either Test, One Day or 20/20.

29. <u>How should ADOs advise the Laboratories of the type of analysis they require on a Sample?</u>

ADOs must ensure that the type(s) of analysis required for each Sample is recorded at a minimum on the chain of custody documentation (or equivalent) shipped with the Samples to the Laboratory or via another system that the ADO has agreed with the Laboratory. This will require that clear instructions are provided to the <u>Doping Control Officer</u> who is authorized to collect the Sample(s).

In certain situations an *ADO* may request further analysis of a *Sample* following the results of another *Sample* collected at the same or an earlier time. As an example, an *ADO* may collect an *ABP* blood *Sample* at the same time as a urine *Sample*, and following the review of the profiles in the *ABP Sample* may request ESA analysis on the urine *Sample*. In such circumstances the *ADO* would have to notify the <u>Laboratory</u> of this request for further analysis (which may be by email). *ADOs* are reminded that *Samples* are routinely stored by <u>Laboratories</u> for a maximum of three months in accordance with the requirements of the *International Standard* for Laboratories.

As per the ISTI the type of analysis shall not to be recorded on the DCF.

30. How will ADAMS be modified to assist ADOs with the implementation of the TDSSA and to report accurate statistics so ADOs and WADA can monitor the implementation of the TDSSA?

WADA will make a number of changes to *ADAMS* to support the implementation of the TDSSA. This includes:

- Disciplines of the sports listed in the TDSSA.
- Following the review of the implementation period of the TDSSA, WADA will consider how the level of Athlete can be recorded in ADAMS and also how ADOs can monitor their TDP progress and compliance with the MLAs.

The *ADAMS* user guide will be updated to provide *ADAMS* users with details of these amendments in due course

31. <u>In the case where an ADO collects Samples as a service provider for another ADO, which ADO is accountable for meeting the MLAs?</u>

In such situations, the organization requesting the Tests, known as the <u>Testing Authority</u>, will be responsible for ensuring it is meeting the required TDSSA MLAs.

Any such plans by the $\overline{\text{TA}}$ to conduct analyses under the TDSSA should be clearly outlined within a *Testing* service agreement. This situation also applies where a *NADO* who is the service provider wishes to conduct additional analysis on *Samples* (at its own cost) that it collects on behalf of an IF or *MEO* under Article 5.2.6 of the WADC2015. In such cases, if the sport/discipline contains MLAs in the TDSSA, then the IF or *MEO* (as the TA) would receive credit for such analyses towards meeting their individual MLA requirements.

32. What if an ADO exceeds the MLAs?

The MLAs are minimums. *ADO*s are encouraged to exceed those minimums if their Risk Assessment or any other relevant information indicates they should do so.

33. Can the MLAs be reduced and, if so, what is the process for obtaining a reduction?

Yes, in accordance with Article 6.4.2 of the WADC2015, an *ADO* can apply to *WADA* for a reduction in the MLAs contained in the TDSSA. Further information on the criteria is located in Article 6 of the TDSSA. The application form can be found in Supporting Document A.

34. What criteria must be met in accordance with Article 6.4.2 of the WADC2015 in order to qualify for a possible reduction in MLAs?

WADA will consider a request for a reduction in MLAs by an *ADO* where such reduction would lead to a more intelligent testing program than compliance with the prescribed MLAs alone. At present, only the implementation of the haematological module of the *ABP* is considered a justifiable criteria for possible reduction given that its operation can be evaluated and subsequently has the potential to be a more intelligent basis for specified analyses than the MLAs prescribed by the TDSSA.

An *ADO* may present a case for possible reduction based on other particular circumstances provided that the *ADO* demonstrates how the reduction of the MLA can support a more intelligent, effective and efficient use of available *Testing* resources. As the implementation of the TDSSA progresses, *WADA* may expand acceptable criteria with more detail as trends develop and consistent applications and common criteria are accepted.

35. <u>Could the TDSSA lead to some ADOs just meeting the minimum percentages and not applying the Tests effectively?</u>

The implementation of the TDSSA and meeting the MLAs is one part of achieving an effective *Testing* program. Whilst the decision of which *Athletes* are selected and the timing of such Tests is at the discretion of the *ADO*, it is important that the decision-making process applied to such Tests is effective in deterring and detecting doping.

A more comprehensive evaluation of an *ADO*'s compliance with the ISTI will include the review of the methods an *ADO* applied to the implementation of the MLAs in the TDSSA. This will be addressed through *WADA*'s wider compliance program.

Prohibited Substances within the scope of the TDSSA & WADA Accredited Laboratories

36. Will the TDSSA have a direct impact on WADA accredited Laboratories' capacity to analyze for those Prohibited Substances within the scope of the TDSSA?

All WADA accredited laboratories can analyze for ESAs in urine and GH (isoforms test) in blood serum.

WADA is undertaking a review of all accredited laboratories to determine the current analytical capacity for each <u>Laboratory</u>.

Where applicable, WADA will identify and encourage the expansion of the necessary capacity within those <u>Laboratories</u> where particular analytical methods are deemed a priority for surrounding regions to implement the TDSSA, and in doing so, attempt to minimize shipping costs.

37. How does an ADO know which WADA accredited laboratory can test for the <u>Prohibited Substances on the TDSSA?</u>

As part of the 2015 *International Standard* for <u>Laboratories</u> (ISL), it is a requirement for Laboratories to publish the costs associated with their *Sample* analysis services. *WADA* will do this in collaboration with the <u>Laboratories</u> and this information will be exclusively available in

ADAMS. From 1 January 2015, ADOs will be able to identify those *Prohibited Substances* or classes of *Prohibited Substances* that each Laboratory can analyze.

This information will only be accessible to *ADO*s that have an *ADAMS* user agreement in place and will be password-protected.

38. What are the analysis methods for GH?

There are two complementary methods for GH analysis: the Isoforms Differential Immunoassays (the GH Isoforms Test) and the GH Biomarkers Test.

The GH Isoforms Test has been applied since the Athens Olympic Games 2004 and commercial test kits have been available to WADA accredited laboratories since 2008. This method has been implemented in all WADA accredited laboratories.

The other method (GH Biomarkers Test) was initially implemented during the 2012 London Olympic and Paralympic Games. However, it is currently undergoing a process of validation of new component assays following the withdrawal from the market of one of its assays. The Test will be initially available to a limited number of accredited laboratories with a gradual implementation among the other Laboratories over time.

These two GH Tests are complementary in nature: while the GH Isoforms Test detects GH doping up to 24-48h after administration, the GH Biomarkers Test, which measures changes in concentration levels of two main markers of GH biological action, namely IGF-1 and P-III-NP, may not detect GH in the initial phase of use but does at later times and for a longer period that the GH Isoforms Test.

It is recommended that once the GH Biomarkers Test is available, *ADO*s conduct both analytical methods when testing for GH as they provide a greater ability to detect GH when applied together.

39. Why are GH and GHRFs grouped together?

Taking into account current limitations in <u>Laboratory</u> capacity for GHRFs, both GH and GHRFs MLAs have been grouped together for the initial implementation of the TDSSA.

As <u>Laboratory</u> capacity increases, these two substance categories may be split and have their own separate MLA requirements.

40. Will ADOs have to apply the MLA percentage to both GH/GHRF or divide it?

It is recommended that the majority of the MLA for GH/GHRF is applied to *Testing* for GH since all Laboratories have the capacity to analyze for GH (via the GH Isoforms Test) and only a limited number of Laboratories are currently offering the GHRFs Test.

In cases where *ADO*s collect a urine *Sample* with a blood *Sample* and the nearest <u>Laboratory</u> does not have a validated GHRF method for urine or blood then, the *ADO* should ship the urine *Sample* to the nearest Laboratory that offers the GHRF Test in urine.

41. <u>Should ADOs store blood serum Samples until the GH biomarkers analysis method</u> becomes available?

Yes. Storing any *Sample* for re-analysis promotes deterrence and further protects clean *Athletes*. Article 4.7.3 of the ISTI outlines that *ADO*s shall incorporate into their <u>TDP</u> a *Sample* retention strategy for the re-analysis of *Samples*. The storing of blood serum *Samples* (after GH Isoforms *Testing*) for re-analysis when the GH Biomarkers Test becomes available is a recommended strategy.

ADOs should contact Laboratories to discuss the logistics around the potential storage of *Samples*.

42. How will the MLA for GH and GHRFs be calculated in meeting the MLA?

If a blood serum *Sample* is analyzed for GH and a urine *Sample* collected from the same *Athlete* during a single *Sample* Collection Session is analyzed for GHRFs, this will count as two analyses towards the GH/GHRFs MLA requirements.

43. The TDSSA outlines that ESAs can be analyzed in urine or blood. Does this mean that an ADO has to collect a blood and urine Sample each time to conduct ESA Testing or can an ADO decide for either blood or urine (and sometimes both)?

The *ADO* has the choice as to whether it wishes to analyze ESAs in <u>either</u> urine <u>or</u> blood. However, it is noted that the detection method for CERA is more effective in blood serum than urine. When <u>Laboratories</u> analyze for CERA in blood serum, they will also be applying methods, such as IEF or SAR-PAGE, capable of detecting other ESAs in addition to CERA (recombinant EPOs, NESP, etc.).

One analysis towards the minimum level requirement shall be counted irrespective of whether a single or multiple ESA analysis is conducted on a urine and/or blood *Sample* collected during a <u>Sample Collection Session</u> on the same *Athlete*.

44. <u>If an ADO has a robust and effective ABP haematological program in place, can it seek a reduction in the MLA for ESAs?</u>

Yes. WADA recognizes that the ABP haematological module is an important tool in implementing effective *Testing* programs for certain sports/disciplines. Therefore an ADO may seek a reduction in the MLA percentage for ESAs if it has implemented an ABP haematological module that meets the specified criteria. A maximum reduction of up to half the ESAs MLA percentage may be granted.

The criteria to apply for a reduction in the MLA for ESAs are outlined in Article 6 of the TDSSA and the application form is contained within Supporting Document A of the TDSSA.

45. The original scope of the TDSSA included Haemoglobin Based Oxygen Carriers (HBOCs), Homologous Blood Transfusion (HBT) and Insulins. Why are these not included in the final version of the TDSSA?

HBOCs and HBT shall be tested on a discretionary but targeted basis applying analytical knowledge gained from the implementation of an effective ABP program and non-analytical intelligence. On the basis of the relative performance benefit, as well as detection efficacy and

health risks of these methods, they were removed from the scope of the TDSSA. This decision remains subject to review. However, this should not prevent any *ADO* to order such *Testing* based on experience and/or intelligence-based targeting.

The inclusion of Insulins in the TDSSA will be delayed on the basis of limited Laboratory analytical capacity. However, ADOs should continue *Testing* those sports and disciplines at risk based on intelligence. Insulins have been known to be used in conjunction with other *Prohibited Substances* such as ESAs and GH and so *Testing* should be focused on those sports and disciplines that are at a high risk to these *Prohibited Substances*.

HBOCs, HBT and Insulins all remain on the *Prohibited List* and are prohibited in all sports and disciplines.

46. Which Samples should be analyzed for HBOCs and HBT?

- HBOCs: any blood Sample collected (either for the ABP or for the detection of Prohibited Substances and/or Methods when an A and B Sample is collected) which shows plasma red coloration beyond reasonable hemolysis after centrifugation or sedimentation;
- HBT: any blood Sample collected (either for the ABP or for the detection of Prohibited Substances and/or Methods when an A and B Sample is collected) which shows a sudden increase of haemoglobin and/or reduction of the percentage of reticulocytes, or Samples collected following sudden drops of haemoglobin and/or increase of the percentage of reticulocytes (which could indicate withdrawal), or if there is a suspicion based on a high phthalates measurement.

47. What should an ADO do if the Laboratories that can analyze GHRFs are a significant distance away from the place of Sample collection?

WADA recognizes that not all <u>Laboratories</u> can currently perform the analysis of GHRFs and that some ADOs will be required to ship their Samples to <u>Laboratories</u> in other regions of the world to analyze for these *Prohibited Substances*.

WADA will focus on increasing <u>Laboratory</u> capacity in those regions where there is an identified need for GHRFs analysis.

48. Will any Prohibited Substances or Prohibited Methods that are included in the WADA Prohibited List be added to the TDSSA in the future or will these new Prohibited Substances or Prohibited Methods be part of the standard routine urine analysis?

Any *Prohibited Substance* or *Prohibited Method* that is added to the *Prohibited List* and has an approved analytical method may be subject to inclusion on the TDSSA as part of its ongoing review and development (if their analysis is not included in the standard routine urine analysis).

Note: ADOs are encouraged to provide WADA with any further questions they may have on the TDSSA or its implementation.