## **MONITORING GROUP (T-DO)**

ANTI-DOPING CONVENTION

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

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# **EVALUATION REPORT OF THE MONITORING GROUP (T-DO)**

# EVALUATION VISIT TO SPAIN 18 – 20 OCTOBER 2022

The Monitoring Group oversees the implementation and application of the Anti-Doping Convention. The Additional Protocol to the Anti-Doping Convention supplements the responsibilities of the Monitoring Group by requiring the Monitoring Group to '*supervise the application and implementation of the Convention*' by the Parties to the Convention.

This supervision is achieved through an integrated compliance approach. A significant component of this is the evaluation process, whereby a team of experts appointed by the Monitoring Group (**Evaluation Team**) examines the implementation of the Convention by a Party and provides a report (**Evaluation Report**) to the Monitoring Group. The Evaluation Team will typically undertake this examination by way of a visit to the Party being evaluated, this visit being referred to as an **Evaluation Visit**.

In October 2022, the Spanish Government invited an Evaluation Team to conduct an Evaluation Visit. Prior to the Evaluation Visit the Spanish authorities submitted a **National Report** which provided detailed description of the measures adopted by the Spanish authorities in relation to the Convention. This Evaluation Report records the outcome of that Evaluation Visit.

This Evaluation Report is divided into two Sections:

Section One A summary of the conclusions reached by the Evaluation Team, identification of best practices that may be of use and benefit to other Parties, and recommendations made to the Spanish Government.

Section Two A detailed set of observations and conclusions of the Evaluation Team.

## SECTION ONE

## A. Executive Summary

The Evaluation Team considered the measures taken by the Spanish Government to comply with the Convention by reference to the National Report and the consultations held with a number of relevant organisations engaged in the overall anti-doping framework in Spain.

These organisations included the Ministries tasked by the Spanish Government with responsibility for sport, civil justice and criminal justice, law enforcement bodies, sport administration bodies including the National Olympic and Paralympic Committees, accredited Laboratories and the National Anti-Doping Organisation.

The Evaluation Team noted that the Spanish Government has adopted various pieces of legislation that have the cumulative effect of implementing the operational provisions of the Convention. In addition, the Spanish Government has established the National Anti-Doping Organisation, CELAD, which has a legal responsibility to fulfil the roles and responsibilities assigned to National Anti-Doping Organisations by way of the World Anti-Doping Code.

The Spanish Government has put into effect a strategy whereby a number of its public authorities collaborate as part of an overall anti-doping framework, coordinated through a National Anti-Doping Platform. These public authorities include the agencies responsible for food, pharmaceutical and medicinal product regulation, law enforcement bodies and customs regulation agencies. This framework is designed to make the exchange and communication of information relating to the sale, supply and distribution of doping agents and devices as effective and efficient as possible.

CELAD has the primary responsibility for ensuring that an effective anti-doping program is operated in Spain, in compliance with the World Anti-Doping Code. It is supported and assisted in this regard by a number of key sporting organisations, including the Supreme Council for Sports, and both the National Olympic and Paralympic Committees.

The Supreme Council for Sports is the primary funder of sports bodies in Spain and requires that sport bodies cooperate with and support CELAD's operational activities. Funding can be withdrawn from any organisation that fails to support CELAD or in some other way fails to comply with the standards encapsulated within the World Anti-Doping Code.

The distribution, sale and supply of banned substances, as well as devices that can be used in connection with doping, is regulated by a number of legislative and regulatory instruments. These include laws restricting the sale and supply of a number of substances, including certain substances that are routinely included each year as part of the Prohibited List (such as anabolic steroids).

A number of 'cross-over' offences exist under Spanish criminal law, which has the effect of making the most serious anti-doping rule violations (such as dealing in and administering banned substances) criminal offences. Spanish law enforcement bodies have achieved notable successes in recent years in identifying and disrupting illicit manufacturing and supply operations in Spain, with the collaboration established through the National Anti-Doping Platform facilitating anti-doping rule violation investigations conducted by CELAD.

CELAD is responsible for the testing of sports persons within Spain, including both domestic sports persons and overseas sports persons who visit Spain to both train and compete. This testing program fulfils the requirements of the Convention and is carried out in compliance with the relevant standards within the World Anti-Doping Code. The analysis of biological samples is conducted by two laboratories, located in Madrid and Barcelona respectively, both of which are accredited by the World Anti-Doping Agency.

CELAD is responsible, in collaboration with partner organisations, for producing and communicating education and training related to anti-doping to sports persons and support personnel. This is conducted in collaboration with sports organisations, in particular the Supreme Council for Sports. The content and reach of the education and training meets the requirements of the Convention, albeit that there is an absence of clarity amongst sports organisations as to the nature of their role in relation to the provision of education and training.

The primary piece of anti-doping legislation in Spain positions CELAD as the principal organisation with responsibility for investigating anti-doping rule violations and bringing forward disciplinary cases. Disciplinary cases are to be resolved by the operationally independent hearing body established by the same law. At the time of the Evaluation Visit the hearing body had not resolved any disputes (being constituted relatively recently); nevertheless, the Evaluation Team did identify one important area of practice that it believes requires attention, in connection with the manner in which disputes are resolved.

A number of these matters are reflected in the Best Practices identified, and Recommendations made, by the Evaluation Team, as below.

## **B.** Best Practices

The Evaluation Team identified the following best practices arising from the measures adopted by the Spanish Government:

- a) The regular use of the National Anti-Doping Platform for facilitating communications and cooperation between public authorities, as well as acting as a central information and data collection repository in relation to compliance reporting, is of significant value. The Terms of Reference and Rules of Procedure used in connection with the National Anti-Doping Platform may be a valuable best practice template.
- b) The lead role taken by the Spanish Agency For Medicines and Sanitary Products (AEMPS) in conjunction with pharmaceutical suppliers as regards product labelling, specifically with regards to patient information enclosed with pharmaceutical products containing information as to the potential doping risks top sports persons associated with the relevant pharmaceutical products, has the potential to reduce the risk of inadvertent anti-doping rule violations occurring.
- c) The lead role taken by the Spanish Agency for Food Safety and Nutrition (AESAN) in relation to the requirement that food supplements must be notified to AESAN in order to be made available for legitimate sale in Spain, and the power delegated to AESAN to order the withdrawal from market of any adulterated, contaminated or otherwise unlawfully manufactured or sourced food supplements, makes a significant contribution to the reduction of doping risk associated with the use of food supplements.
- d) The close collaboration between CELAD and law enforcement bodies is a striking example of modern integrated best practice whereby different agencies with an overlapping brief and jurisdiction cooperate in relation to their different areas of authority and jurisdiction. This includes the participation within CELAD of officers deployed/assigned from the Spanish police authorities. The success of this approach is highlighted by the fact that CELAD has been involved in several police investigations involving public health offences that involved sports persons.
- e) CELAD's leading role in the development of the 'NoDop' application designed for Spanish and Portuguese speaking sports persons is an important best practice in terms of assistance and development support provided to nations with less developed anti-doping frameworks.

f) The establishment of the "*Red Iberoamericana de Lucha Contra el Dopaje*" (RILD), the Ibero-American Anti-Doping Network, is an essential tool to mutually reinforce NADOs. The leading role taken by CELAD to establish and ensure the sustainability of the Network is a good practice.

## C. Recommendations

The Evaluation Team makes the following recommendations arising from the measures adopted by the Spanish Government in connection with the Convention:

- i. In relation to anti-doping education and training, the NOC and NPC shall develop their own anti-doping education and information strategies regarding the provision of information and training, complementary to and supportive of those pursued by CELAD.
- ii. In relation to Testing, that the Spanish authorities and CELAD shall review what operational measures may need to be taken so that effective Testing of Spanish athletes who are located outside of Spain, particularly those training in North Africa, can take place.
- iii. In relation to research, a strong collaboration between the two Laboratories (for example by the provision of joint research funding) shall ensure that the funding, resources and expertise of both Laboratories is utilised in a coordinated manner.
- iv. In relation to governance, the practice whereby the President of the Supreme Council for Sports is automatically appointed to be President of the CELAD Governing Council shall be reviewed to ensure that no actual or perceived conflicts of interest arise.
- v. In relation to disciplinary matters, the anticipated practice of resolving disputes by way of written representations and documents alone is not considered to be an optimal model. Resolving anti-doping disciplinary disputes by way of consideration of written materials should be a means of resolving a dispute if it is available as an alternative to an in-person hearing, whereby parties are able to present their case, provide testimony and evidence, and cross-examine such testimony and evidence. In this regard it is also recommended that anti-doping hearings should, at the hearing panel's discretion, be held in public.

## SECTION TWO

Prior to the Evaluation Visit the Spanish Ministry of Culture and Sport, in conjunction with the Spanish National Anti-Doping Organisation, provided a National Report (Annex 2) detailing the various measures taken by the Spanish Government to implement the Convention.

This Section of the Evaluation Report has been prepared by the Evaluation Team and constitutes a detailed description of its findings by reference to the relevant sections of the National Report and the matters identified during the course of the Evaluation Visit (Annex 1).

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## 1. Legislation, Regulations and Administrative Provisions

- 1.1. The National Report (Annex 2) provides a detailed description of the legislative measures adopted by the Spanish Government in relation to the Convention. In relation to the Convention itself, the Spanish Government signed the Convention in 1989 and ratified it in 1992. It signed and ratified the Additional Protocol to the Convention in 2017.
- 1.2. The primary piece of enabling legislation in relation to anti-doping practice and operations is Law 11/2021 on the prevention and fight against doping in sport which came into force on 28 December 2021 (orig.: Ley Orgánica 11/2021, de 28 de diciembre, de lucha contra el dopaje en el deporte), referred to as the **Organic Law 11/2021**, enacted in part to ensure that the Spanish anti-doping framework is compatible with the World Anti-Doping Code. The Organic Law provides the basis for the annual update of the International Standard for the Prohibited List and the institutional presence and role of the National Anti-Doping Organisation.
- 1.3. Subsequent to the Evaluation Visit, the Spanish Government adopted Royal Decree 908/2022 which gave effect to a number of subsidiary instruments relating to the anti-doping framework in Spain, including the operational regulations of the National Anti-Doping Organisation.
- 1.4. The Spanish Government has adopted a number of legislative and regulatory instruments that have a direct bearing on the application of the Convention. These are referred to in this Evaluation Report and include measures within the Spanish criminal justice system that make certain aspects of 'doping behaviour' a criminal offence, most particularly the dealing in Prohibited Substances in circumstances where that dealing constitutes a risk to public health. This resonates directly with the founding principles of the Convention, which specifically refer to the risk to health of participants in sport caused by the use of doping agents and methods.

## 2. National Anti-Doping Organisation (NADO) – Structure and Governance

- 2.1. The precursors to the Organic Law provide the legislative base for the Spanish National Anti-Doping Organisation, being the Spanish Commission for the Fight Against Doping in Sport (CELAD). CELAD's status and identity as the National Anti-Doping Organisation for Spain is repeated and ratified within the Organic Law.
- 2.2. The Spanish Government has overseen a national anti-doping program in Spain for a number of years, which has involved a number of public authorities, including in particular the Supreme Council for Sports, referred to below in this Report.
- 2.3. Prior to the formation of CELAD, the former agency for health protection in sport (AEPSAD) performed the functions of the National Anti-Doping Organisation in Spain (taking on this role from 2008), in addition to a number of other duties. As per the Organic Law, AEPSAD's health and sport responsibilities were assigned to the Supreme Council for Sports, with AEPSAD being reconstituted as CELAD.
- 2.4. CELAD is responsible for fulfilling the roles assigned in the World Anti-Doping Code to National Anti-Doping Organisations. CELAD is a public authority and regulated by the relevant governmental instruments concerning such entities (this is explained further in the National Report). Senior staffing appointments are drawn primarily from the Spanish civil service.
- 2.5. CELAD is overseen by a 'Rector Board' and a 'Control Commission' with the President of the 'Rector Board' being the President of the Supreme Council for Sports (CSD) (further information concerning the CSD is included at Section 3.2.5 below). A 'Rector Board' is a feature of Spanish public authority structures such as CELAD. The CELAD Rector Board is referred to as the 'Governing Council' within the overall CELAD governance structure.
- 2.6. The 'Governing Council' is appointed through a process overseen by and accountable to the Ministry of Culture of Sport. The President of the Governing Council is ultimately responsible for appointing the Chief Executive of CELAD. It is responsible for approving senior level appointments within CELAD, as well as overall budget approval and the adoption of final accounts (this is a typical role assigned to 'Rector Boards' such as the Governing Council). The Governing Council also has a key role in preparing and agreeing the operational budget for CELAD with the Ministry of Culture and Sports. This process is explained in the National Report (Annex 2, Section 2.2).
- 2.7. In addition, CELAD is subject to supervision by a 'Control Commission', an ancillary body appointed by and reporting to the Governing Council in relation to economic and financial matters. Its role is essentially to ensure that CELAD's operations are both adequately financed and that CELAD stats within its annual operational budget. The budget allocated to CELAD for 2022 was reported to be approximately Euro 9 million, with the budget allocated to CELAD for 2023 (national budget and European Union grant) to be above Euro 11 million as it also included the budget of the Madrid antidoping laboratory and the national sports medicine centre. It is expected that CELAD budget in 2024 will be substantially reduced as it will solely finance the NADO-related activities.
- 2.8. The Evaluation Team was advised that a number of senior roles within CELAD were required to be filled by civil servants with a specific minimum grade and level of experience, and that in certain instances these roles were filled on a fixed-term basis. The Evaluation Team noted that there were general public administration reasons underpinning this policy, which appeared to be a general policy adopted across a number of public authorities. There is a risk, the Evaluation Team noted, that an unintended consequence of such a policy is that its rigidity may deny CELAD the expertise and experience of key personnel.

2.9. The Evaluation Team did not note any significant concerns as regards the compatibility of CELAD's governance structures with the Convention or the Monitoring Group Recommendation as to the Operational Independence of National Anti-Doping Organisations. The governance structures are, it was noted, large in relation to comparable National Anti-Doping Organisations, but it was also noted that the structure applied to CELAD is a feature more of Spanish public authority organisation than a specific structure adopted specifically in relation to CELAD.

#### Recommendation

2.10. In relation to governance, the practice whereby the President of the CSD is ex officio also the President of the CELAD Governing Council shall be reviewed to ensure that no actual or perceived conflicts of interest arise.

#### 3. Public Authorities

- 3.1. It is a familiar feature of public administration that a number of agencies can be engaged in operational activities that overlap with each other, and/or contribute to similar overall goals and strategies. It is not always the case that these agencies work in cooperation regarding such operations. The Spanish Government has adopted a policy whereby its public agencies engaged in operations relevant (either directly or indirectly) to anti-doping are encouraged to collaborate and share information, experiences and learnings. This is explained in the National Report (Annex 2, Section 3.1.1).
- 3.2. The National Report refers to a number of public bodies that are expressed to be stakeholders in the fight against doping in sport. These stakeholders are described in detail in the National Report (Annex 2, Section 3.1). The following bodes play a distinctive role within the general anti-doping framework in Spain:
  - 3.2.1. **AEMPS**: the Spanish Agency for Medicines and Medical Devices (AEMPS). AEMPS regulates the distribution of medicinal devices and pharmaceutical products in Spain. The relevant regulations are enforced by AEMPS through a combination of seizures, investigations and online enforcement. AEMPS collaborates with the suppliers of pharmaceutical products as regards product labelling, specifically with regards to patient information enclosed with pharmaceutical products containing information as to the potential doping risks top sports persons associated with the relevant pharmaceutical products (for example, the product 'Testex' includes such a warning given that it contains testosterone, a Prohibited Substance). AEMPS operates within a network of agencies, including CELAD, and the two organisations routinely exchange information that is potentially relevant to their operational work.
  - 3.2.2.**AESAN**: the Spanish Agency for Food Safety and Nutrition (AESAN) includes within its designated authority the regulation of food supplements. Food supplements are required to be notified to AESAN in order to be made available for legitimate sale in Spain, with AESAN having the power to order the withdrawal from market of any adulterated, contaminated or otherwise unlawfully manufactured or sourced food supplements. Information concerning illicit supplements is shared with CELAD by AESAN, and CELAD also provides information to AESAN in relation to any supplements that have been identified through its anti-doping investigations as being potentially in contravention of supplement regulations.
  - 3.2.3.**Customs**: Spanish customs officials are active in the pursuit of unlawfully imported medicinal and pharmaceutical products, including counterfeit products. Customs officials collaborate closely with AEMPS, in that the importation of medical equipment and related products into Spain is subject to notification and registration requirements administered

by AEMPS. Customs officials are most active at international points of entry into Spain such as airports, ports and postal hubs (the Evaluation Team noting that the open borders associated with the Schengen area have a limiting effect on the ability to completely restrict the importation of medicinal and pharmaceutical products). There is a close cooperation between Customs officials and CELAD as regards the exchange of information relating to the unlawful dealing in of medicinal and pharmaceutical products.

- 3.2.4.**Law Enforcement:** the National Police and the Civil Guard are the two main law enforcement agencies engaged in the investigation and detection of offences associated with the illegal sale, supply and distribution of doping substances and related materials. As noted at paragraph 3.3 below, each agency has formalised cooperation arrangements with CELAD, which include a representative from each agency working within CELAD on a seconded basis. (Both the National Police and the Civil Guard are ultimately accountable to the Spanish Government Ministry of the Interior.)
- 3.2.5. Ministry of Justice: the Ministry of Justice is a significant stakeholder in the overall antidoping framework, arising in connection with criminal and administrative offences established within the Spanish criminal justice system in relation to 'public health'. Public health is the basis of anti-doping policy in that the illicit sale, supply and distribution of doping substances is recognised as a serious public health issue. A range of offences, including those related to medicine abuse, misuse of medical devices and the manipulation of sport performances exist in circumstances where there is a 'risk to public health/life'. If the circumstances that give rise to public health offences take place at the same time as other related offences such as supply and distribution, with the offence that carries the highest sanction being pursued. Possession of restricted substances is not generally criminalised, and 'mere' use of a banned substances does not constitute an offence. The investigation of such offences is undertaken by law enforcement officers. CELAD is obliged to share information with law enforcement bodies if its investigations identify evidence relating to the commission of a criminal offence. In practice this relates only to trafficking and administration related offences. CELAD has been involved in several police investigations relating to public health offences that involved sports persons. These generated a number of cases against sports persons. As noted further in this Report the presence of law enforcement personnel seconded to CELAD makes a significant contribution to the efficient sharing and exchange of information as between CELAD and law enforcement agencies.
- 3.2.6.**Supreme Council for Sports**: the Supreme Council for Sports (**CSD**) is a division within the Ministry of Culture and Sport, with a number of sport administration and regulatory responsibilities. These include the provision of funding support to National Federations (and equivalent bodies) for sports. Funding to National Federations is by way of grant on application primarily for an Olympic cycle, as well as funding provided to sports persons. Financial support is contingent on compliance with anti-doping regulations. The CSD has an express obligation to work with CELAD.
- 3.3. CELAD enjoys a level of close cooperation and engagement with the public authorities mentioned above, and those referred to in the National Report. In particular, CELAD incorporates officers deployed/assigned from the Spanish police authorities on a seconded basis, namely the National Police (*Policía Nacional*) and the Civil Guard (*Guardia Civil*). The Evaluation Team was provided with an extensive presentation delivered by the representatives of law enforcement bodies that emphasis the utility of this cooperation.
- 3.4. The Evaluation Team was provided with a breadth of statistical information that illustrates the amount of activity undertaken by the Spanish public authorities in relation to the identification and seizure of doping substances and materials. The Civil Guard has a lengthy track record in this area as evidenced by numerous operations and substances seizures. The National Police

referred to its Operations Barinas, Skype, Jimbo and Chamberi which resulted in, respectively, 11, 10, 42 and 22 arrests being made. (Similar statistics were provided by the Spanish Customs.) Both police forces are collaborating in joint operations with a particular focus on the dismantling of clandestine laboratories producing doping substances.

- 3.5. There is both synergy and complementarity between the administrative and penal systems, in that the severity of potential sanctions (i.e., what is the most severe offence charged with) determines where the system is heard. The Ministry of Justice explained that there are mechanisms in place to ensure that CELAD provides information to relevant authorities for follow-up in the penal system, and similarly to require judges to inform CELAD of possible administrative infractions for follow-up.
- 3.6. Whilst the penal and administrative systems are separate and focusing on different infractions, mechanisms are in place to ensure flow of information and cooperation, enhanced by the presence of law enforcement officers within CELAD. This is a positive element.
- 3.7. The public authorities engaged in operations related to anti-doping have established a National Anti-Doping Platform, which is explained in detail in the National Report (Annex 2, Section 3.1). The National Anti-Doping Platform is expressed to be a vehicle to facilitate communications and cooperation between public authorities, as well as acting as a central information and data collection repository in relation to compliance reporting. The National Anti-Doping Platform provides an important facility for information exchange and consultation amongst the participating public authorities.

## **Best Practices**

- 3.8. The lead role taken by AEMPS in conjunction with pharmaceutical suppliers as regards product labelling has the potential to reduce the risk of inadvertent anti-doping rule violations occurring, specifically with regards to patient information enclosed with pharmaceutical products containing information as to the potential doping risks to sports persons associated with the relevant pharmaceutical products.
- 3.9. The lead role taken by AESAN in relation to the requirement that food supplements must be notified to AESAN in order to be made available for legitimate sale in Spain, and the power delegated to AESAN to order the withdrawal from market of any adulterated, contaminated or otherwise unlawfully manufactured or sourced food supplements, make a significant contribution to the reduction of doping risk associated with the use of food supplements.
- 3.10. The close collaboration between CELAD and law enforcement bodies is a striking example of modern integrated best practice whereby different agencies with an overlapping brief and jurisdiction cooperate in relation to their different areas of authority and jurisdiction. This includes the participation within CELAD of officers deployed/assigned from the Spanish police authorities. The success of this approach is highlighted by the fact that CELAD has been recently involved in several police investigations involving public health offences that involved sports persons.
- 3.11. The regular use of the National Anti-Doping Platform for facilitating communications and cooperation between public authorities, as well as acting as a central information and data collection repository in relation to compliance reporting is of significant value. The Terms of Reference and Rules of Procedure used in connection with the National Anti-Doping Platform may be a valuable best practice template for other Governments looking to adopt a similar model.

## 4. Sport Organisations

- 4.1. CELAD enjoys a close level of cooperation and collaboration with the key sporting organisation stakeholders in Spain, in particular the CSD, the National Olympic Committee (NOC) and the National Paralympic Committee (NPC). Persons who wish to participate in sport at a high/elite level are required to have a licence, with the terms for such licencing including a commitment to comply with anti-doping regulations. This licencing framework facilitates in turn the provision of education and training to sports persons.
- 4.2. There is an established process whereby sanctions are applied to sports persons who commit anti-doping rule violations in respect of any funding that such persons receive (indirectly or directly) from the CSD, the NOC or the NPC. This is explained in detail in the National Report (Annex 2, Section 3.1.2).
- 4.3. The NOC and NPC have a general responsibility for assisting CELAD in the fulfilment of CELAD's roles and responsibilities under the World Anti-Doping Code. National Federations (and equivalent bodies) are required to be members of the NOC/NPC in order for athletes from their sports to be eligible for selection to represent Spain at the Olympic/Paralympic Games. This membership is contingent on compliance with the relevant International Federation Anti-Doping Rules, the IOC/IPC Anti-Doping Rules and the World Anti-Doping Code, although compliance management and oversight are generally reactive rather than proactive. A number of codes of conduct regulate the relationships between the NOC, NPC and their members.
- 4.4. The NOC did not appear to be fully engaged in the overall process of educating and training Athletes and Athlete Support Persons as to matters concerning anti-doping. This is, in part, a reflection of the overlapping responsibilities between the NOC and CELAD as referred to in the Code. Nevertheless, the Convention anticipates that a collaborative approach should be taken by sports organisations to educational and informational programmes concerning the health risks of doping and its harm to the ethical values of sport. A closer level of engagement as far as the provision of education and training by the NOC would, therefore, be desirable. While not covering all anti-doping issues, the NPC took measures to promote the fight against doping among athletes, in particular through the "plan adop" which formalises the relation as between the NPC and Athletes and Athlete Support Persons.
- 4.5. The provision of education and training in relation to anti-doping is perceived by the CSD, the NOC and the NPC to be primarily the role of CELAD, with the CSD, the NOC and the NPC providing practical assistance where appropriate. This view appears to extend to National Federations. In this regard, it was reported that there is a perceived absence of clarity within the World Anti-Doping Code standards (in particular Article 7 of the International Standard for Education) as to the extent of anti-doping education responsibilities. This results in a degree of confusion as to both accountability and provision responsibility in terms of education. This is not, it was reported, an issue that appears to be confined to Spain.
- 4.6. The CSD has agreements with National Federations (and other sports organisations) that have the effect of making the receipt of funding conditional on those organisations complying with their anti-doping responsibilities. As noted in this Report, the CSD does not undertake any active compliance role in this regard but is empowered to respond to concerns brought to its attention by CELAD, should any such arise.

#### Recommendation

4.7. The NOC and NPC are recommended to develop their own education and information strategies, complementary to and supportive of those pursued by CELAD, regarding the provision of information and training concerning anti-doping matters.

## 5. Restricting the Availability of Doping Substances

- 5.1. The Spanish Government has enacted a range of legislative and regulatory instruments that address the illicit sale, supply and distribution of certain substances. These instruments include regulations that restrict the distribution of Prohibited Substances, with different instruments being applicable according to the nature of the particular Prohibited Substance. These are described in detail in the National Report (Annex 2, Section 5).
- 5.2. These instruments concern matters such as the sale and supply of medicines, pharmaceutical products, medical devices and other sanitary material (such as counterfeited face masks of inferior quality). The responsibility for investigating such offences falls primarily to the National Police and Civil Guard. The law enforcement authorities have been successful in identifying and closing down a number of clandestine facilities engaged in the manufacture and supply of Prohibited Substances.
- 5.3. As noted above, the annual update of the Prohibited List is brought into effect in Spain each year by publication in the Official Bulletin (BOE) and thereby incorporated into the Organic Law. This ensures that sports persons are subject to the current version of the Prohibited List on a rolling basis.

## 6. Testing and the Analysis of Biological Samples

## **Doping Control**

- 6.1. CELAD is the primary Testing agency in Spain. The National Report explains the specifics of CELAD's operations in this regard including matters such as the extent and scope of the Testing program undertaken by CELAD, the Testing budget and Test Distribution Plan, in some detail.
- 6.2. The Test Distribution Plan used by CELAD is dynamic and is based on information received, generated and prepared by the NADO's intelligence division. CELAD uses the services of third-party providers (Verun, Víctor Roldán and PWC) to support the domestic Testing Plan. A further provider, IADS, supports the non-domestic Testing Plan.
- 6.3. CELAD manages the recruitment, training, certification and performance of Doping Control Officers according to recognised International Standards relating to quality assurance through third-party providers.
- 6.4. CELAD has signed cooperation agreements with numerous NADOs to facilitate the Testing of Spanish athletes residing or training outside the country. CELAD advised that it encounters difficulties in testing Athletes notably in athletics in certain countries, in particular in North Africa. Whilst these difficulties are primarily operational, the Evaluation Team was informed that a Royal Decree was currently under revision to alleviate the requirements for testing abroad.
- 6.5. CELAD utilises DIOCLES, a bespoke software application, to support the operation of the Testing program. This encompasses a paperless doping control process and integrates the Testing program with related actions and information across CELAD's operations. The DIOCLES application is used as it is understood to possess a wider functionality than the commonly used ADAMS platform administered by the World Anti-Doping Agency. DIOCLES is being developed in order to improve interoperability with similar systems used by other Anti-Doping Organisations.

- 6.6. CELAD has been successful in attracting European Union funding to develop a Plan of Modernization and Digitization of the Anti-Doping Fighting between 2022 and 2024. Part of this funding will be for the further development of the DIOCLES system.
- 6.7. The Evaluation Team noted that the World Anti-Doping Agency has raised a small number of operational issues regarding the Test Distribution Plan adopted by CELAD, although none of these compromised compliance with the Convention.

#### **Analysis of Biological Samples**

- 6.8. There are two Laboratories in Spain accredited by the World Anti-Doping Agency in respect of the analysis of biological samples, located in Madrid and Barcelona (referred to in this Report for simplicity's sake as 'the Madrid Laboratory' and 'the Barcelona Laboratory').
- 6.9. The Madrid Laboratory (Laboratorio de Control del Dopaje de Madrid) is well supported by CELAD in that it provides virtually all of its anti-doping Samples to that Laboratory for analysis. At the time of the Evaluation Visit, CELAD and the Madrid Laboratory existed under the same administrative 'umbrella' within the Spanish Government, which the Evaluation Team was concerned might raise issues of perception as far as the independence of the Madrid Laboratory was concerned. In this regard, the Spanish Government has, subsequent to the Evaluation Visit, completed the necessary administrative steps to separate the sponsoring ministries for CELAD and the Madrid Laboratory which now operates under the "Carlos III" Health Institute Research a public biomedical research institution under the Minister of Science and Innovation.
- 6.10. The Madrid Laboratory analyses approximately 7,000 Samples per annum, with a peak of 8,747 in 2019, but considers that it has the capacity to analyse 10,000. It has 28 experienced staff members. It is adequately equipped with analytical instruments although has only one high resolution mass spectrometer (it appeared that there may be issues with the acquisition of new instruments). It also has appropriate space for the long-term storage of samples.
- 6.11. The Barcelona Laboratory (the Catalonian Antidoping Laboratory) has an APMU (Athlete Passport Management Unit) approved by WADA and provides this service for CELAD. It receives most of its biological samples from outside of Spain. Like the Madrid Laboratory it analyses more than 7,000 per annum and considers that it has the capacity to analyse 10,000.
- 6.12. Detailed information regarding the composition and staffing levels of each of the Laboratories is contained within the National Report.

#### Recommendation

6.13. It is recommended that the Spanish authorities and CELAD review what operational measures may need to be taken that effective testing of Spanish athletes who are located outside of Spain, particularly those training in North Africa, can take place.

## 7. Education and Research

#### Education

- 7.1. CELAD operates a comprehensive anti-doping education and training program utilising a number of individual components and modules. It is closely integrated with the other main sport stakeholders in Spain in this regard.
- 7.2. The National Report details a number of the programs run by CELAD (Annex 2, Section 7.1). The Evaluation Team received sufficient information in relation to these programs during the

course of the Evaluation Visit to be satisfied that the requirements of the Convention were being met by the Spanish Government.

7.3. CELAD utilises 12 national level educators, including former athletes, who provide education sessions. As noted above, there is a level of confusion stemming from the World Anti-Doping Code and related standards as to the levels of responsibility that fall to the varying sport stakeholders when it comes to the provision of anti-doping education. There is recognition, for example, from CSD that it is required to ensure the cooperation of National Federations and other sport organisations with CELAD so as to facilitate the provision by CELAD of anti-doping education and training. There is less of an understanding as to what is required in terms of such provision by the same National Federations and other sport organisations.

## **Best Practice**

7.4. CELAD's leading role in the development of the 'NoDop' application designed for Spanish speaking sports persons is an important best practice in terms of assistance and development support provided to nations with less sophisticated anti-doping frameworks.

## Research

- 7.5. The National Report provides a significant amount of detail as to the research exercise and projects conducted under the auspices of CELAD and the Laboratories (Annex 2, Section 7).
- 7.6. The Barcelona Laboratory provides a training and consultancy service helping many new sports analytical laboratories obtain accreditation. It has close connections with universities especially the Universitat Pompeu Fabra (UPF) in Barcelona; Laboratory staff teach on a variety of programmes and also support Masters and PhD students. It has an excellent research output, in the period 2015-2021 it recorded over 300 scientific publications, more than 30 PhDs and more than 30 Masters students.
- 7.7. The Evaluation Team noted that one notable feature of research is on collaboration with health institutions into 'positive' research as to the health benefits of certain medicines and substances.

## Recommendation

7.8. In relation to research, a strong collaboration between the two Laboratories (for example by the provision of joint research funding) should be envisaged to utilise the funding, resources and expertise of both Laboratories in a coordinated manner.

## 8. Disciplinary Measures

- 8.1. CELAD has the primary responsibility pursuant to the Organic Law for investigating antidoping rule violations and initiating disciplinary proceedings against sports persons who are alleged to have committed anti-doping rule violations. These disputes will generally concern the commission or otherwise of an anti-doping rule violation and/or the consequences (as that term is used in the Organic Law) that fall to be imposed in relation to an anti-doping rule violation.
- 8.2. The dispute resolution body established in relation to anti-doping rule violation matters is the Anti-Doping Sanctioning Committee (ADSC). CELAD has the responsibility of bringing proceedings before the ADSC.
- 8.3. The ADSC is comprised of seven members, appointed for a four-year term. The Evaluation Team understood that the ADSC is considered by WADA to be compatible with the requirements of the World Anti-Doping Code as regards the Operational Independence of the

ADSC is concerned. The Evaluation Team did not have any concerns arising from the Monitoring Group Recommendation as to Hearing Panels.

- 8.4. Given its recent establishment the ADSC had not, at the time of the Evaluation Visit, resolved any anti-doping rule violation disputes brought before it pursuant to the Organic Law.
- 8.5. It appears from consultations conducted during the Evaluation Visit that disputes brought before the ADSC will be resolved solely on the basis that the parties to a dispute (which will usually be, on the one side, CELAD, and on the other, an athlete or athlete support person) will make written submissions to the ADSC, with the dispute being resolved on the basis of those submissions. This appeared to exclude the possibility of there being the more usual 'inperson' hearing format whereby the parties to a dispute appear in person before a hearing panel, present their evidence and witnesses, and allow an opportunity for evidence and witnesses to be tested by way of verbal examination.
- 8.6. Appeals made by either party in relation to a decision of the ADSC are resolved by the ADSC. A further right of appeal to the Administrative Court exists, as provided by Spanish administrative legislation.

#### Recommendation

8.7. In relation to disciplinary matters, the anticipated practice of resolving disputes brought before the ADSC by way of written representations and documents alone is not considered to be an optimal model. Resolving anti-doping disciplinary disputes by way of consideration of written materials could be a means of resolving a dispute if it is available as an alternative to an inperson hearing, whereby parties are able to present their case, provide testimony and evidence, and cross-examine such testimony and evidence. In this regard it is also recommended that anti-doping hearings should, at the hearing panel's discretion, be held in public.

#### 9. International Co-operation and Provision of Information

- 9.1. The Convention emphasises the importance of coordination and cooperation among States Parties to the Convention at the international level. A main channel for such cooperation is the Monitoring Group of the Anti-Doping Convention (T-DO) and the Ad hoc European Committee for the World Anti-Doping Agency (CAHAMA), which is responsible for the coordination of the positions of all States Parties to the European Cultural Convention, with regard to questions and policy relating to WADA, WADA policies and WADA's operational activities.
- 9.2. The Spanish Government and CELAD attend and/or is consistently represented at the meetings of the T-DO as well as the meetings of CAHAMA. At an operational level, the Evaluation Team was made aware that CELAD collaborates with many Anti-Doping Organisations (other European and American NADOs, law enforcement authorities from other countries, Interpol and Europol and international federations). CELAD participates as National Expert within the structures of the Medicrime Convention of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No. 211).
- 9.3. As noted above, it also has a leading role in the development of the 'NoDop' application designed for Spanish and Portuguese speaking sports persons.
- 9.4. CELAD took a leading role in establishment of the Ibero-American Anti-Doping Network ("*Red Iberoamericana de Lucha Contra el Dopaje*"- RILD) in 2021 by being one of the 23 founding NADOs and providing the secretariat to the Network. RILD has been created with the aim to consolidate itself as a worldwide reference representing the cultural and structural commonalities of fight against doping in the region. In addition, the RILD also aims at

providing technical assistance and supporting knowledge transfer between its member organisations (including support for the establishment of a NADO for those countries where the National Olympic Committee is still acting as the NADO), to promote initiatives for adequate communication and collaboration among NADOs, to establish links with other stakeholders, and to execute projects of mutual interest.

## **Good practice**

9.5. The establishment of RILD, the Ibero-American Anti-Doping Network, is an essential tool to mutually reinforce NADOs. The leading role taken by CELAD to establish and ensure the sustainability of the Network is a good practice.

## Annex 1 – Evaluation Team and programme of the visit

## **EVALUATION TEAM**

Pia HASCHKE Head of the Evaluation Team Chair of the European Ad Hoc Committee for the World Anti-Doping Agency (CAHAMA) Head of Unit, Departmental Legal Affairs, Sport Department, Federal Ministry for Arts, Culture, the Civil Service and Sport Austria

Graham ARTHUR Rapporteur Independent Expert, Anti-Doping Lawyer United Kingdom

Sara-Ioana SARAGEA Chief of staff, Office of the President, Romanian National Anti-Doping Agency (ANAD) Romania

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Professor Emeritus in Pharmaceutical Toxicology, Former Director of the Drug Control Centre, Department of Analytical, Environmental & Forensic Sciences, King's College London United Kingdom

Mr Martin HOLMLUND LAUESEN Director, International Relations and Medical, Anti-Doping Norway (ADNO) Norway

#### Secretariat

Julien ATTUIL-KAYSER Head of the Anti-Doping Unit, Sport Division, Council of Europe

Leonor TEJADO HINOJO Anti-Doping Unit, Sport Division, Council of Europe

## Observer

Olympia KARAVASILI Manager, Government and NADO Relations, European Office, WADA

## PROGRAMME OF THE VISIT AND STAKEHOLDERS MET

Day1 -	Tuesday, 18 October 2022
9:00h	Welcome and opening of the evaluation visit by the Director of the Spanish Commission for the Fight Against Doping in Sport (Comisión Española para la Lucha Antidopaje – CELAD). Structure and governance of CELAD. Attendees: • Evaluation Team
	<ul> <li>José Luis Terreros – Director of CELAD</li> <li>Ramón Sánchez – General Secretary of CELAD</li> <li>Carlos Gea – Head of the International Relations and Cooperation Area of CELAD</li> </ul>
10:00h	Meeting with the Doping Control Department.
	Attendees:
	<ul> <li>Evaluation Team</li> <li>José Luis Terreros – Director of CELAD</li> </ul>
	<ul> <li>Ramón Sánchez – General Secretary of CELAD</li> <li>Jesús Muñoz– Guerra – Head of the Doping Control Department of CELAD</li> <li>Carlos Gea – Head of the International Relations and Cooperation Area of CELAD</li> </ul>
11:00	Coffee Break
11:30h	Meeting with the Education Department.
	Attendees:
	<ul> <li>Evaluation Team</li> <li>José Luis Terreros – Director of CELAD</li> </ul>
	<ul> <li>Ramón Sánchez – General Secretary of CELAD</li> <li>Jesús Garrido – Head of the Education Department of CELAD</li> </ul>
	$\cdot$ Carlos Gea – Head of the International Relations and Cooperation Area of CELAD
12:00h	Meeting with the Legal Affairs Division.
	Attendees:
	<ul> <li>Evaluation Team</li> <li>José Luis Terreros – Director of CELAD</li> </ul>
	<ul> <li>Ramón Sánchez – General Secretary of CELAD</li> <li>Rosa Godino – Head of the Legal Affairs Division of CELAD</li> <li>Carlos Gea – Head of the International Relations and Cooperation Area of CELAD</li> </ul>

12:30h	Meeting with the International Relations and Cooperation Area.								
	Attendees: • Evaluation Team • José Luis Terreros – Director of CELAD • Ramón Sánchez – General Secretary of CELAD • Carlos Gea – Head of the International Relations and Cooperation Area of CELAD								
13:00h	Joint meeting with Spanish Olympic Committee (COE) and Spanish Paralympic Committee (CPE). Attendees: • Evaluation Team • Victor Sánchez (Treasurer) – COE • Mª Rosario Ureña (Scientific and Medical Committee) – COE • Miguel Carballeda (President) – CPE • Alberto Jofre (Managing Director) – CPE • José Luis Terreros – Director of CELAD • Ramón Sánchez – General Secretary of CELAD • Carlos Gea – Head of the International Relations and Cooperation Area of CELAD								
14:00h	Lunch break.								
16:00h	Joint meeting with: Spanish Agency for Medicines and Medical Devices (AEMPS), Spanish Agency for Food Safety and Nutrition (AESAN).								
	Attendees:								
	<ul> <li>Evaluation Team</li> <li>Manuel Ibarra (Head of the Pharmaceutical Inspection and Enforcement Department) – AEMPS. Ministry of Health.</li> </ul>								

	<ul> <li>Victorio Teruel (Deputy Director– General for Food Safety Management) – AESAN. Ministry of Consumer Affairs.</li> <li>José Luis Terreros – Director of CELAD</li> <li>Ramón Sánchez – General Secretary of CELAD</li> <li>Carlos Gea – Head of the International Relations and Cooperation Area of CELAD</li> </ul>
16:40h	Joint meeting with: Deputy Directorate of Customs Surveillance of the Department of Customs and Special Taxes (State Agency of Tax Administration), General Directorate of the General State Administration in the Territory (Ministry of Territorial Policy and Public Function), Pharmaceutical Inspection Services at Customs and Foreign Health Services at Customs.
	Attendees:
	<ul> <li>Evaluation Team</li> <li>Jose Luis Valle (Head of the Intelligence and Information Area) – Deputy Directorate of Customs Surveillance of the Department of Customs and Special Taxes.</li> <li>Francisco R. Andrés Suárez (Head of the Security and Safety Area) – Deputy Directorate of Customs Surveillance of the Department of Customs and Special Taxes.</li> <li>Marta Noval (Head of Area) – General Directorate of the General State Administration in the Territory. Ministry of Territorial Policy and Public Function.</li> <li>M<sup>a</sup> José Grajera (Head of Service) – Pharmaceutical Inspection Service at Madrid-Barajas Airport</li> <li>Ana María Sanz (Head of International Goods Control Area - Deputy Directotate General for Foreign Health) – Ministry of Health</li> <li>Gema Santiago – Foreign Health Coordinator at Madrid-Barajas Airport</li> </ul>

- · José Luis Terreros Director of CELAD
- · Ramón Sánchez General Secretary of CELAD
- · Carlos Gea Head of the International Relations and Cooperation Area of CELAD

## Day 2 – Wednesday, 19 October 2022

9:00h	Meeting wit	h Ministry	of Justice.

#### Attendees:

- Evaluation Team
- · Josefa Navarro (Office of the Minister of Justice) Ministry of Justice
- Mario Maraver (Office of the Minister of Justice) Ministry of Justice
- Rosa Godino Head of the Legal Affairs Division of CELAD
- José Luis Terreros Director of CELAD
- · Ramón Sánchez General Secretary of CELAD
- · Carlos Gea Head of the International Relations and Cooperation Area of CELAD

## 10:00h Travel to the Supreme Council for Sports (CSD).

## 10:30h Meeting with the Supreme Council for Sports (CSD).

#### Attendees:

- Evaluation Team
- · Conchi Bellorín Deputy to the General Director of Sports. Supreme Council for Sports
- José Luis Terreros Director of CELAD
- · Ramón Sánchez General Secretary of CELAD
- · Carlos Gea Head of the International Relations and Cooperation Area of CELAD

11:30h	Meeting with Anti-doping Laboratories.
	Attendees: • Evaluation Team • Gloria Muñoz – Director of the Anti-doping Laboratory in Madrid
	<ul> <li>Rosa Ventura – Director of the Anti-doping Laboratory in Madrid</li> <li>José Luis Terreros – Director of CELAD</li> <li>Ramón Sánchez – General Secretary of CELAD</li> <li>Carlos Gea – Head of the International Relations and Cooperation Area of CELAD</li> </ul>
12:30h	Return to CELAD.
13:00h	Meeting with the Anti–Doping Sanctioning Committee (CSA).
	Attendees:
	<ul> <li>Evaluation Team</li> <li>Rafael Cabellero – President of the CSA</li> <li>Ramón Sánchez – General Secretary of CELAD / Secretary of the CSA</li> <li>José Luis Terreros – Director of CELAD</li> <li>Carlos Gea – Head of the International Relations and Cooperation Area of CELAD</li> </ul>
14:00h	Lunch break.
16:00h	Joint meeting with National Police and Civil Guard. Intelligence and Investigations.
	Attendees:
	<ul> <li>Evaluation Team</li> <li>Patricia Angulo (Captain) – Civil Guard</li> <li>Santiago Rivera (Captain) – Civil Guard</li> </ul>
	<ul> <li>Miguel Ángel Marcos (Warrant officer) – Civil Guard</li> <li>Juan José Castro (Chief Inspector) – National Police</li> </ul>
	<ul> <li>Juan Pablo Armenteros (Inspector) – National Police</li> <li>Lucía Ferrero (Officer) – National Police.</li> </ul>
	<ul> <li>José Luis Terreros – Director of CELAD</li> <li>Ramón Sánchez – General Secretary of CELAD</li> <li>Carlos Gea – Head of the International Relations and Cooperation Area of CELAD</li> </ul>
17:30h	End of the day.

## Day 3 – Thursday, 20 October 2022

#### 9:30h Wrap up meeting with CELAD.

#### Attendees:

- Evaluation Team
- Juan Martorell (Deputy Director for International Relations President's Cabinet) Supreme Council for Sports
- José Luis Terreros Director of CELAD
- Ramón Sánchez General Secretary of CELAD
- $\cdot\,$  Carlos Gea Head of the International Relations and Cooperation Area of CELAD

## 11:00h Coffee and end of the evaluation visit.

## Annex 2- National report





# NATIONAL REPORT SPAIN

# Anti-Doping Convention

## COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

October 2022



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## 0. INTRODUCTION

Spain signed the Council of Europe Anti-doping Convention in 1989 and ratified it in 1992. It further ratified in 2017 the Additional Protocol to the Anti-doping Convention.

Representatives of Spain have been actively participating in several projects and groups of the Monitoring Group of the Convention (T-DO) to improve the fight against doping across Europe.

The last T-DO evaluation visit to Spain took place in 2011, and considerable changes and improvements have been made in the anti-doping system in Spain since then. Due to our tireless efforts to comply with the 2021 World Anti-doping Code, Spain was included among the countries to receive an evaluation visit in 2022-2023.

On 11th February 2022, the Director of CELAD received a letter from Michael Petrou, in which he challenged us to host an evaluation visit, preferably during the second semester of 2022.

We appreciate the evaluation visit very much and are all well aware that it provides an external assessment of the anti-doping program, and allows us to benefit from the vast experience and knowledge of the T-DO experts through a dedicated exchange of information and expertise.



## 1. PART ONE: LEGISLATION, REGULATIONS AND ADMINISTRATIVE PROVISIONS

## 1.1. IMPLEMENTATION OF THE ANTI-DOPING CONVENTION / LEGISLATIVE, REGULATORY AND/OR POLITICAL AND POLICY MEASURES

Accordingly with the International Convention against doping in sport of UNESCO of 2005, which was ratified by Spain in 2006, the National Anti-doping Organization in Spain, the **Spanish Commission for the Fight Against Doping in Sport** (Comisión Española para la Lucha Contra el Dopaje en el Deporte - CELAD) has undertaken appropriate measures in order to comply with the World Anti-doping Program to promote the prevention and the fight against doping in sport, with a view to its elimination.

At the same time, these measures have implemented the correlative provisions of the Antidoping Convention of the Council of Europe specifically concerning measures to restrict the availability and use of banned doping agents and methods, cooperation with sports organizations on measures to be taken by them, and organizing educational programs in cooperation with sports organizations.

At the end of 2021, 28th December, the <u>Organic Law 11/2021</u>, of December 28, on the fight against doping in sport, was approved by the Spanish Parliament. The main reason for the approval of the new Law was to update the anti-doping regulatory framework that was contained in the <u>Organic Law 3/2013</u>, of June 20, on the protection of the health of the athlete and the fight against doping in sporting activity, and to adjust the Spanish anti-doping legislation to the dispositions contained in the World Anti-doping Code 2021.

The objectives of the new Law are:

- More effectiveness in the elimination of doping practices in sports and in the protection of athletes' health.
- Strengthen and intensify anti-doping measures
- Clarify and specify the objective and subjective scope of the Law
- Adopt measures that benefit a more effective inspection of athletes that try to alter sports competition rules.
- Modify the sanctioning regime with more proportionate and efficient measures according to international legislation.

The main new measures adopted are the following:



- a. Separate the specific competencies in fighting against doping in sports that concerns exclusively the CELAD from the health protection of athletes that concerns the Supreme Council of Sports.
- b. A new classification of athletes includes the "amateur athlete" that has an attenuated sanctioning regime.
- c. New definitions as "protected person" as the one who is minor of 16, 18 years old, or that has no legal or behave capacity that have a sanctioning regime attenuate and abuse substances that have and adjust sanctioning regime.
- d. The Anti-doping Sanctioning Committee is an independent body that is in charge of the resolution of the sanctioning proceedings.
- e. Any reliable method or any other athlete matrix authorized by the World Anti-doping Agency can confirm the existence of anti-doping infractions.
- f. All the anti-doping infractions have the same level. The previous classification of serious and very serious infractions has disappeared.
- g. Athlete support personnel and staff from sporting clubs, federations, teams, and leagues.... could be disqualified forever if they facilitate doping substances to protected persons.
- h. The amount for the pecuniary sanctions has increased considerably.
- i. It is included a list of aggravating circumstances.
- j. Specific rules of evidence include an adverse result in the biological passport of the athlete. An adverse result in the biological passport of the athlete constitutes evident proof of the existence of the infraction of article 20 b) of the Organic Law 11/2021.
- k. Sanctioning resolutions will be published disclosing:
  - Name of the athlete
  - The anti-doping rule violated
  - The prohibited substance or prohibited method involved
  - The consequences imposed
  - The sport
- I. The Anti-doping Sanctioning Committee will be the body in charge of the sanctioning resolutions.

Now, we are working with the Sport and Culture Ministry on the project of a Royal Decree that will develop the dispositions contained in the <u>Organic Law 11/2021</u> to adequate the commitments and procedures of the CELAD to the referred law. At the same time new rules concerning the Therapeutic Use Exemptions (TUE), doping control process, test distribution



planning, and whereabouts of athletes will be established in accordance with international regulations.

The project will also develop the functioning rules of the Anti-doping Sanctioning Committee, the rules of the Biological Passport of the Athlete, and the procedure to impose and revise the disciplinary doping sanctions.

## **1.2. ESTABLISHMENT OF THE NATIONAL ANTI-DOPING ORGANISATION**

The <u>Organic Law 7/2006, of 21 November, on the protection of health and the fight against</u> <u>doping in sport</u>, created for the first time a Spanish Anti-doping Organization. Later, successive Anti-doping Organic Laws <u>3/2013</u> and <u>11/2021</u> have been relevant measures to set up the Spanish anti-doping Organization, as it is at the moment, according to international regulations.

## **1.3. PROHIBITED LIST**

The International Convention against doping in sport of UNESCO contains in its Annex I the Prohibited List. As this International Convection has been ratified by Spain, it is directly applicable so each year the successive <u>versions of the list are published in the Official State Bulletin</u> and consequently enter into force in the Spanish territory.

Apart from the above referred, the Organic Law 11/2021 in article 21 concerning sanctions mentions the List of prohibited substances and methods as compulsory.





## 2. PART TWO - NATIONAL ANTI-DOPING ORGANISATION (NADO) – STRUCTURE AND GOVERNANCE

# 2.1. CONSTITUTION AND LEGAL STATUS OF CELAD/ INDEPENDENCE AND GOVERNANCE OF CELAD

The new Organic Law 11/2021, of December 28, on the fight against doping in sport, incorporates into the Spanish legislation the 2021 World anti-doping Code and establishes the Spanish Commission for the Fight Against Doping in Sport (CELAD) as a state autonomous agency attached to the Ministry of Culture and Sport.

CELAD is the state agency responsible for the effective application of the anti-doping policies in Spain in accordance with the World Anti-doping Code (WADA), the International Convention against Doping in Sport (UNESCO), and the anti-doping Convention (Council of Europe).

CELAD is a public law entity, as provided for in Article 108 bis.1 of <u>Law 40/2015</u>, of October 1, <u>on the Legal Regime of the Public Sector</u> and regulated in Section 4 of Title II, Chapter III of the aforementioned Law 40/2015, of October 1.

CELAD has a public legal personality, its own assets, and treasury and management and functional autonomy, within the limits established by Law 40/2015, of October 1.

CELAD is attached to the Ministry of Culture and Sport through the Superior Council of Sports. Correspond to that Ministry the strategic direction, evaluation, and control of results of the activity of the State Agency Spanish Commission for the Fight against Doping in Sport. These functions will be exercised through the monitoring and control of the management contract, for which purpose it will establish the necessary coordination procedures for the proper exercise of the powers and responsibilities arising from the assignment of the CELAD to the Ministry of Culture and Sport, in accordance with the provisions of Article 85 of Law 40/2015, of October 1.

Like all State Agencies, CELAD is empowered with the mechanisms of functional autonomy, responsibility for management, and control of results established in Law 40/2015, of October 1.

CELAD's governing bodies are the Presidency and the Governing Council. The Presidency of CELAD and its Governing Council is the holder of the Supreme Council of Sports (CSD). The Governing Council is the collegiate governing body of CELAD and will be composed of the person holding the Presidency of the Agency, who will also be the President of the CSD, and a number of councillors, who will be appointed by the Minister of Culture and Sport.



The executive body of CELAD will be its Director, who will be appointed and removed by the Governing Council at the proposal of the holder of the Presidency from among career civil servants belonging to bodies and scales of Subgroup A1, with accredited experience in public management in the field of sports or in the areas of competence of CELAD.

Within the organizational structure, CELAD is made up of the following departments:

Department of Doping Prevention Policies in Sport.

In charge of the management, planning, and execution of anti-doping education and scientific research activities.

- <u>Doping Control Department.</u>
   In charge of the management, planning, and execution of doping controls and related activities.
- General Secretary.

In charge of the management and administrative direction of the human, economic, financial, computer, logistic, and material resources of CELAD.

CELAD also has the following commissions:

Control Commission.

In charge of economic-financial control and reporting to the Governing Council on related aspects.

Anti-Doping Coordination Commission.

CELAD's participation, coordination, and monitoring body in which athletes will be represented as well as the competent bodies and agencies of the autonomous regions in the fight against doping in sport.

Other bodies:

Anti-Doping Sanctioning Committee.

Specific body of the Agency in sanctioning matters and which, with a high degree of administrative and operational independence in the adoption of its decisions, is the competent body to resolve the sanctioning proceedings for doping infractions foreseen in the law and which also hears the special administrative appeal referred to in article 47 of Organic Law 11/2021, of December 28, on the fight against doping in sport, as well as appeals in matters of granting or denial of Therapeutic Use Exemptions.



## **Recruitment and appointment of senior officials at ONAD**

In view of the special responsibility, technical competence, and relevance of the tasks assigned, the following will be considered as managerial personnel: the Director, the Secretary-General, and the heads of the departments. The posts of Secretary General and the Head of the Department of Doping Prevention Policies in Sport will be occupied by a career civil servant belonging to a body or scale of Subgroup A1.

The position of Head of the Department of Doping Control will be occupied in the labour regime through a senior management contract, in accordance with the provisions of Article 108 quater of Law 40/2015, of October 1. Senior management personnel who have the status of a civil servant or labour will remain in the situation of active service in their respective body or scale or in that which corresponds under labour legislation, respectively.

The Director of CELAD is also considered a Senior Officer for the purposes of the provisions of Law 3/2015, of March 30, regulating the exercise of senior positions in the General State Administration, although he/she must be appointed from among career civil servants belonging to bodies and scales of Subgroup A1.

## 2.2. FUNDING OF THE CELAD

CELAD is financed, like the rest of the public bodies, through state transfers (99%). The remaining funding comes from the provision of services (currently the taking of samples) to sports federations, organizers of sporting events, and other public and private entities, or through other public or private income that it is authorized to receive.

These budgetary allocations are established annually through the approval of the General State Budget Law. The current budget law is Law 22/2021, of December 28, of the General State <u>Budget for the year 2022</u>. This law bases its regulatory framework on both the <u>Spanish</u> <u>Constitution of 1978</u> and the General Budgetary Law (Law 47/2003, of November 26) and the Organic Law on Budgetary Stability and Financial Sustainability (Organic Law 2/2012, of April 27, on Budgetary Stability and Financial Sustainability).

It is important to highlight that the expenditure budget of the state agencies is limited by its overall amount and is estimated for the distribution of credits in economic categories, with the exception of those corresponding to personnel expenses, which in any case are limited and binding for their total amount, and of the nominative subsidies and protocol and representative attention, which will be limited and binding whatever the level of the economic classification at which they are established.



The Agency's budgets are basically divided into two large blocks. On the one hand, we find the block of the <u>budgetary expenses</u> and the <u>budgetary revenues</u>.

The <u>budgetary expenses</u> include the following types of expenditure:

- Personnel Expenses (salaries, social security, passive rights,...).
- Current Expenditures on Goods and Services (supplies, maintenance, services,...)
- Current Transfers (WADA quota, iNADO quota, agreements with Universities,...)
- Investment Expenses (purchase of machinery, facilities, or other inventoriable material,...).

In order to meet all these expenses, the <u>budgetary income</u> received by the Agency is as follows:

- Income from the provision of services (Sampling and analysis of the Laboratory that are outside the Annual Control Plan).
- Current Transfers from the State Administration (These finance personnel expenses, current expenses in goods and services, and current transfers).
- Capital Transfers from the State Administration (Finance investment expenses).

The budgetary regime of the Agency is likewise established in Article 108 sexies the Law 40/2015, of October 1, on the Legal Regime of the Public Sector. The Governing Council shall prepare and approve the preliminary draft budget of the Agency, in accordance with the provisions of the management contract. The preliminary draft budget of the agency will be sent to the Ministry of Culture and Sports for its examination, which will subsequently transfer it to the Ministry of Finance. Once analysed by the latter ministerial department, the preliminary draft budget is incorporated into the General State Budget for its approval by the Council of Ministers and submission to the Spanish Parliament, consolidating it with that of the other entities comprising the State public sector.

The execution of the budget of the state agencies corresponds to their executive bodies, which prepare and send to the Control Commission, on a monthly basis, a budget execution statement.



## 3. PART THREE - PUBLIC AUTHORITIES

## **3.1. PUBLIC AUTHORITIES / COORDINATION OF PUBLIC AUTHORITIES**

## 3.1.1. Information Sharing and Exchange between Public Authorities

Since the creation of AEPSAD in 2013 and since the new agency CELAD in 2021, we had maintained a very close relationship with all the stakeholders that have any kind of involvement in some aspect of the fight against doping in sport.  $\checkmark$ 

From CELAD, we are very aware that, due to the nature of doping in sports, the only option that allows its adequate prevention and repression is a multidisciplinary and multi-sectoral approach for the detection, communication, investigation, sanction, and criminalization of this type of practices. The lack of communication, information exchange, and joint operational actions gives, individuals or organizations involved in this type of illicit practices, the opportunity to carry out their activities with impunity and represents a waste of time and resources for the parties involved.

That is why CELAD considered it particularly important to establish a joint strategy for the prevention and fight against doping that improves and strengthens the collaboration between the parties involved. The different parties have their own competencies, expertise, and jurisdiction, which creates the perfect framework for cooperation and information exchange between the parties.

With this and other objectives in mind, a **National Anti-doping Platform (NADP)** was created in 2021, which integrates all the actors involved in the fight against doping in sport in Spain:

- CELAD Ministry of Culture and Sport
- Supreme Council for Sports (CSD) Ministry of Culture and Sport
- Spanish Agency for Medicines and Medical Devices (AEMPS) Ministry of Health
- Spanish Agency for Food Safety and Nutrition (AESAN) Ministry of Consumer Affairs
- General Directorate of the General State Administration in the Territory (Pharmaceutical Inspection Services and Foreign Health Services of the Health and Social Policy Areas of the Government Delegations) - Ministry of Territorial Policy and Public Function.
- State Secretariat of Justice Ministry of Justice
- National Police Ministry of the Interior
- Civil Guard Ministry of the Interior



- State Agency of Tax Administration (Deputy Directorate of Customs Surveillance of the Department of Customs and Special Taxes) - Ministry of Finance.
- Spanish Olympic Committee (COE)
- Spanish Paralympic Committee (COE)
- Athletes' representatives

The main objective of the NADP is to facilitate adequate communication, coordination, cooperation and collaboration among the entities with competencies directly or indirectly related to the prevention and fight against doping in sport, and the defense of fair play, favouring a multidisciplinary and multi-sectoral approach for the detection, communication, investigation, sanctioning or criminalization of practices associated with doping in sport.

It was also created with the objective of ensuring a consolidated approach to information sharing and data collection relating to the Anti-doping Convention of the Council of Europe, the UNESCO International Convention against Doping in Sport and the World Anti-Doping Code and associated standards of the World Anti-Doping Agency, for harmonized, accurate and inclusive reporting of all measures taken at the national and international level.

Allow us to include a summary of the roles of the different stakeholders mentioned above in the fight against doping in sport:

## 1. Supreme Council for Sports (CSD) - Ministry of Culture and Sport:

The Superior Council of Sports, is an autonomous body belonging to the Ministry of Culture and Sport, which possesses the state competencies related to sport in Spain.

According to the Royal Decree 355/2018 of 6 June, restructuring ministerial departments corresponds to the Ministry of Culture and Sport the proposal and implementation of government policy regarding sport, through the CSD.

The competences of the CSD are established in Law 10/1990, of 15 October, on Sport, and some of them have a clear relation with in relation with the fight against doping in sport.

CSD is responsible for the authorization and revocation of the motivated constitution and adoption of the statutes and regulations of the Spanish Sports Federations, and also the agreement with their objectives, sports programmes, especially those of top-level sport, budgets and organizational structures and functional, adhering to the effect the corresponding conventions.

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CSD is also the entity behind the grant of economic subsidies to sports federations and other entities and sports associations, inspecting and checking their adequacy and the fulfilment of the established requirements including the ones regarding anti-doping.

CSD promotes and encourages measures for the prevention, control and repression of the use of prohibited substances and illegal methods designed to artificially increase the physical capacity of sportsmen and women or to modify the results of competitions.

The President of the CSD holds the Presidency of the CELAD with the following functions:

- a. To hold the institutional representation of the CELAD.
- b. To preside over the Governing Board, as well as to ensure the execution of its agreements, holding all the other powers that correspond to him/her as the Person holding the Presidency of the collegiate body in accordance with the provisions of Article 19 of Law 40/2015, of 1 October.
- c. To oversee the development of the activities of the CELAD, ensuring compliance with the present Statute.
- d. To report to the Ministries of Culture and Sport and of Finance and Public Function, on the execution and fulfilment of the objectives set out in the management contract.
- e. To enter into contracts and agreements of special institutional relevance, within the scope of its competence and after having been delegated.

# 2. Spanish Agency for Medicines and Medical Devices (AEMPS) - Ministry of Health

The Spanish Agency for Medicines and Medical Devices (AEMPS), as a state agency attached to the Ministry of Health, is responsible for guaranteeing to society, from a public service perspective, the quality, safety, efficacy, and correct information on medicines and medical devices, from their research to their use, in the interest of the protection and promotion of human health, animal health, and the environment.

The Department of Inspection and Control of Medicines of the AEMPS has an Area of Illegal Medicines in charge of carrying out all actions intended to combat the trafficking and marketing of illegal and counterfeit medicines, many of which are medicines that include doping substances.

It is responsible for the withdrawal from the market of illegal and falsified medicines and also of illegal adulterated or contaminated food supplements that could be considered medicinal products due to their content in pharmaceutical active ingredients.



## 3. Spanish Agency for Food Safety and Nutrition (AESAN) - Ministry of Consumer Affairs

The Spanish Agency for Food Safety and Nutrition (AESAN) integrates and carries out functions related to food safety and healthy nutrition. It is an Autonomous Body, attached organically to the Ministry of Consumer Affairs, through the General Secretariat for Consumer Affairs and Gambling, and functionally to the Ministry of Consumer Affairs, the Ministry of Health and the Ministry of Agriculture, Fisheries and Food.

Its main objective is to protect health by promoting food security and healthy nutrition.

AESAN acts as the national reference center for assessing, managing and communicating food risks.

It is the entity responsible for the management of the National Plan for Official Control of the Food Chain.

In relation to doping in sport, AESAN has the central database of food supplements that are notified and legally commercialized in Spain, and it is also responsible for the withdrawal from the market of adulterated, contaminated or illegally commercialized food supplements.

4. <u>General Directorate of the General State Administration in the Territory (Pharmaceutical</u> <u>Inspection and Foreign Health Services of the Health and Social Policy Areas of the</u> <u>Government Delegations) - Ministry of Territorial Policy and Public Function.</u>

Pharmaceutical Inspection Services and Foreign Health Services in customs are the public authorities in charge of carrying out customs sanitary controls of medicinal products for human use, including their bulk and intermediate products, active pharmaceutical ingredients, medical devices, and on food and food supplements respectively. This includes the control of postal parcels, as well as the inspection of baggage when civil guard detect the introduction into the country of unusual quantities of substances, medicines, food supplements or other similar products.

## 5. <u>State Secretariat of Justice - Ministry of Justice</u>

The Ministry of Justice is a very important authority to collaborate with, given that the offence against public health related to doping activities established in article 362 quinquies of the Penal Code may be related to administrative offences in the field of doping established in Organic Law 11/2021, of December 28, on the fight against doping in sport.

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The criminal offence of Article 362 quinquies of the Penal Code is an offence against public health, while the administrative offences of Article 20 of Organic Law 11/2021 violate fair play and equal conditions in sporting competitions.

In this context, Article 31 of Organic Law 11/2021 determines the relations and collaboration that must exist between the judicial authorities and the CELAD in the framework of criminal and administrative sanctioning procedures.

- 6. National Police Ministry of the Interior
- 7. Civil Guard Ministry of the Interior

National Police and Civil Guard are the main state security forces and bodies. Both have specific groups dedicated to the fight against illicit medicines trafficking and doping in sport.

CELAD has reached an agreement with both forces to integrate a qualified person from both forces in its intelligence and investigations division.

8. <u>State Agency of Tax Administration (Deputy Directorate of Customs Surveillance of the</u> <u>Department of Customs and Special Taxes) - Ministry of Finance.</u>

The Deputy Directorate of Customs Surveillance is in charge of the coordination of customs and para-customs controls, including sanitary controls of medicines, health products and food supplements.

CELAD maintains close collaboration with customs surveillance to increase customs controls on imports of products containing substances banned in sports, especially small mail shipments sent from countries considered to be at special risk.

- 9. <u>Spanish Olympic Committee (COE)</u>
- 10. Spanish Paralympic Committee (CPE)

The COE and CPE are responsible for assisting and collaborating with CELAD in the implementation of anti-doping policies in the country and the fulfilment of all its obligations under the Anti-Doping Convention, the International Convention against Doping in Sport and the WADA's Code and the International Standards.



CELAD is also part of the **Spanish Cooperation Network of the MEDICRIME Convention** of the Council of Europe.

The creation of this network in Spain was promoted by the Secretary of State for Justice, the current representative to the Council of Europe of the <u>Convention on the counterfeiting of</u> <u>medical products and similar crimes involving threats to public health (MEDICRIME Convention)</u> and the national contact point.

In application of Article 17 of the MEDICRIME Convention, the Ministry of Justice has promoted a national cooperation network with the different experts on trafficking and counterfeiting of medical products and similar crimes involving threats to public health,

in order to prevent and combat effectively these crimes through appropriate cooperation and exchange of information between all the stakeholders.

This collaboration network is currently composed by the Executive Secretary of the Committee of the Parties (CoP) of the MEDICRIME Convention and national experts from the AEMPS, National Police, Civil Guard, CELAD, Customs, university experts, Eurojust, etc.

Additionally, CELAD has a close collaboration with the Health Inspection Services of the Autonomous Regions which is mainly carried out with the Pharmaceutical, Medical and Consumer Inspection Services, and includes:

- Procedure for the control of illicit prescription and pharmaceutical dispensing of medicines susceptible to diversion for use by athletes and other persons involved in sports activities, with the aim of increasing physical or sports performance.
- Detection of falsification of documents provided by athletes in sanctioning procedures (prescriptions, medical reports, etc.).
- Detection of food supplements and illegal dietary products with substances prohibited in sports.
- Inspection of Health Centres (Hospitals EPO/HGH, Sports Medicine Clinics or offices, offices of general practitioners or specialists), Doctors, Pharmacy Offices and Wholesale Warehouses (diversion of medicines). Preparation of reports by Pharmaceutical and Medical Inspectors.
- Detection of the consumption of prohibited substances and the use of prohibited methods in sport, and identification of athletes who consume or use them, as well as possible coaches, doctors or other parties involved.
- Detection and control of inappropriate medical practices and doping in athletes.



## 3.1.2. Eligibility to receive public funding

Spanish athletes can receive financial aid from different public or private institutions. At the national level, the Supreme Sports Council currently has several financial aid programmes for athletes in collaboration with the Spanish Sports Federations, the Spanish Olympic Committee and the Spanish Paralympic Committee.

The criteria required for the granting of aid and scholarships are set out in Annex I of the Resolution of the Presidency of the Supreme Sports Council, on aid regulations for sportsmen and women who participate in official international competitions representing Spain, granted by the Spanish Sports Federations.

Specifically in point 4 of this Annex I relating to "Rights and obligations of the beneficiaries" it is indicated that the beneficiaries will be obliged, during the period of receipt of the aid, to comply with the following:

III. To abide by the federative rules on sporting discipline and doping, and must collaborate at any time they are requested to do so. Athletes will have their grants suspended if they have tested positive in a doping control or have been subject to disciplinary sanction. Athletes shall have their benefits terminated if, as a result of doping control proceedings, the Athlete's sanction is final.

*IV.* To submit to the medical checks and examinations and to the doping controls -both on the occasion of the competition and out of competition- that are required of them through the Federation or other sports bodies competent to do so. To this effect, the scholarship holder accepts to know the list of prohibited substances and methods, approved by CELAD and WADA, which are in force or become valid during the period of enjoyment of the scholarship.

Likewise, in its Annex III, relating to the "Rules applicable to the rules of the Spanish sports federations for the granting of aid to athletes", the following obligations are established as part of the minimum content of the regulatory rules of the scholarships established by these Federations, as obligations of the scholarship holders:

To undergo medical checks and examinations and doping controls, both during and outside competition, as required by the Federation or other competent sporting bodies. To this effect, the acceptance of the scholarship will entail knowledge of the list of prohibited substances and methods, approved by the competent national and international bodies, which is in force or will be in force during the period of enjoyment of the scholarship.

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It is also indicated that a final sanction for doping is grounds for revocation of the scholarship, and if it is not final, the suspension will be applied until its final resolution.

The economic aid programmes of the CSD in collaboration with the Spanish Sports Federations, the Spanish Olympic Committee and the Spanish Paralympic Committee are:

# 1. CSD Team Spain Grants:

The CSD grants this aid to athletes and their coaches for Olympic preparation, which must be applied for by the respective Spanish Sports Federations according to the annual call for applications.

# 2. <u>CSD aid for sporting results:</u>

The CSD grants this aid to athletes for international results, which must be applied for by the respective Spanish Sports Federations in accordance with the annual call for applications. The required criteria appear in Annex II of the aforementioned Resolution of the Presidency of the CSDon aid regulations for sportspersons who participate in official international competitions on behalf of Spain, granted by the Spanish Sports Federations.

In Annex II of the aforementioned Resolution on Regulations on aid for sportspersons, regarding Rules for the granting of "CSD aid results", point 2, which establishes the conditions for the granting of aid, specifically states that:

*b)* Aid will not be granted for results obtained in the following cases:

(b) Where the Athlete has received a final sanction for a doping or sports discipline violation. If at the time of determining the granting of the aid, a final decision has not yet been handed down, the granting of the aid will be suspended until such time.

3. Support for Spanish athletes participating in international competitions:

They must be requested by the respective Spanish Sports Federations in accordance with the annual call for applications.

4. <u>Aid to promote the social protection of top-level sportsmen and sportswomen by covering</u> the cost of their social security contributions:

To be applied for by the respective Spanish Sports Federations according to the annual call for applications.



#### 5. TEAM SPAIN ELITE Programmes:

The CSD grants this aid for Olympic and Paralympic preparation, which must be applied for by the respective Spanish Sports Federations according to the annual call for applications. The criteria required for an athlete or team to be classified in one of the Programmes are included in the Resolution of the Presidency of the CSD, which classifies the TEAM SPAIN ELITE Sports Programmes of the Spanish Sports Federations.

## 6. ADOP Programme:

Grants to athletes and their coaches to support Paralympic preparation. The contract of commitment signed by the athletes with the Spanish Paralympic Committee for the granting of the scholarships includes mandatory clauses relating to the anti-doping policy, which include, from the commitment not to use prohibited substances or prohibited methods, to the submission to anti-doping controls and the revocation of the scholarship in the event of non-compliance with the anti-doping regulations.

Likewise, CSD grants other subsidies to the Spanish Sports Federations, for the financing of their own scholarship and aid programmes.





## 4. PART FOUR - SPORTS ORGANIZATIONS

#### 4.1. NATIONAL OLYMPIC AND PARALYMPIC COMMITTEES

The <u>Organic Law 3/2013</u>, of June 20, on the protection of the health of the athlete and the fight against doping in sporting activity, configures Spanish NADO as the public body that brings together all the competences on doping at a national level, which the previous system distributed among different entities such as the Spanish Olympic Committee (SOC), Spanish Paralympic Committee (PSC) or the National Sports Federations.

This means that since the entry into force of this <u>Organic Law 3/2013</u>, both the SOC, SPC, and the National Sports Federations no longer have competences against doping at a national level.

However, both entities are signatories of the World Anti-Doping Code and contain in their statute (<u>SOC statute</u>, <u>SPC statute</u>) respect of the anti-doping regulations and their commitment to the fight against doping, as well as the collaboration with the public authorities.

The SOC in its statutes also undertakes to ensure the respect and application of the antidoping rules by the Spanish Sports Federations, the athletes and other members of the delegations competing on behalf of the Spanish Olympic Committee, and all the members of the Spanish Olympic Committee.

In this sense, both the SOC and the SPC include among the clauses of the contracts they sign with athletes and other members of the olympic and paralympic delegations the obligation to respect the anti-doping regulations, including allowing the performance of doping controls when required, and non-compliance is grounds for termination of the contract.

## 4.2. NATIONAL SPORT FEDERATIONS

The Organic Law 11/2021 in article 5.2 states that the Government will establish a general framework of collaboration with the sports entities and National Sport Federations in order to facilitate the execution of the anti-doping public policies.

In relation to the role of the National Sport Federations in the application of doping sanctions, it is important to note that the decisions of the sanctioning procedures are communicated to



the sanctioned athlete, to the Supreme Council for Sports, to the National Sport Federation to which the athlete belongs or has belonged, to the corresponding International Federation and to the World Anti-Doping Agency.

The decision on the sanction is sent directly to the Athlete. In the case of the Supreme Council for Sports and the respective National Sports Federation, an official notification is sent to the respective institutions. In the case of the International Federation and the World Anti-Doping Agency, the sanction is notified through the ADAMS platform.

If the Athlete is sanctioned with suspension of the federation licence or ineligibility to obtain it, once the official notification is received, the National Sport Federation suspends the federation licence or will not grant it if the sanctioned Athlete applies for it.

On the other hand, from a practical point of view, the exchange of information that we have with National Sport Federations facilitates in certain circumstances the detection of athletes at higher risk of using prohibited substances or methods, due to their competitive level, unexpected or sudden high performance, injury, or suspicious results in routine medical tests, etc. This information can be very useful for planning targeted testing for these athletes in circumstances that facilitate doping practices or for conducting investigations.





# 5. PART FIVE - RESTRICTING THE AVAILABILITY OF DOPING SUBSTANCES

The convenience on the part of the Spanish State to carry out a coordinated and multidisciplinary fight to restrict the availability, including trafficking, of banned substances and methods in sport arises from the proliferation in Spain of:

- Illegal medicines containing substances whose consumption may pose a risk to the health of athletes and persons engaged in sporting activity, including substances prohibited in sport:
- Products containing pharmacologically active substances that could confer them the legal status of medicines, the consumption of which may pose a risk to the health of athletes and persons involved in sports activities, including substances prohibited in sport (e.g. adulterated food supplements or with declared active ingredients).
- The acquisition of medicines outside the legally established channels for their custody, conservation and dispensation.
- The use of drugs outside their therapeutic indications authorised in their technical data sheet.
- The use of active ingredients in athletes that are in the preclinical or clinical research phase without the required authorization (e.g. GHRH, sermorelin, tesamorelin, AICAR, etc.).
- The use of synthetic drugs and other psychotropic and narcotic substances (e.g. cocaine, THC and other cannabinoids).
- The use of veterinary drugs in humans.
- The use of medical devices for the manipulation of blood and/or blood components, or for any other practice prohibited in sport (e.g. blood bags).

<u>Organic Law 11/2021, of 28 December, on the fight against doping in sport</u>, revises and updates the regulatory and organisational framework for the control and supervision of doping products that prevails in our country.

Article 20 of the aforementioned Organic Law 11/2021, of 28 December, on doping offences, includes all the offences stipulated in the World Anti-doping Code, including, among others, the following offences related to the use or trafficking of prohibited substances and methods:

- Use or attempted use by an athlete of a prohibited substance or a prohibited method
- Possession of a prohibited substance or a prohibited method
- Trafficking or attempted trafficking in any prohibited substance or prohibited method
- Administration or attempted administration of a prohibited substance or prohibited method.
- Etc.



Organic Law 11/2021, of 28 December, also provides for inter-administrative cooperation between CELAD and other public bodies with specific competences in the field of medicines (Spanish Agency for Medicines and Medical Devices, AEMPS) and food, including food supplements (Spanish Agency for Food Safety and Nutrition, AESAN). These are health authorities with which, in Article 14 of the CELAD Statute, point 4.h) calls for collaboration in the development and implementation of activities for the prevention and detection of suspected doping behaviour in sporting activity.

Along with Organic Law 11/2021 of 28 December, it is important to consider other laws directly related to the control of medicines, health products and food supplements and the competent entities in each case:

Law 14/1986, of 25 April 1986, General Health Act.

Article 95. The circulation of unauthorised or unapproved medicinal products or medical devices shall not be prescribed and shall be considered clandestine, with the administrative and criminal liability that may be applicable.

<u>Royal Legislative Decree 1/2015, of 24 July, approving the revised text of the Law on guarantees and rational use of medicines and medical devices.</u>

Article 8. Legally recognised medicinal products. Article 9. Authorisation and registration. Article 111. Infringements in the field of medicinal products. Article 112. Infringements regarding medical devices. Article 114. Penalties.

Medicinal products, due to their special characteristics, have to be evaluated and authorised before being marketed in order to guarantee the right of citizens to health protection.

However, there are certain products that, due to their composition or indications, are true medicinal products but have not been subjected to the mandatory legal procedures, thus constituting a risk to the health and rights of consumers.

By virtue of the powers legally attributed to it by <u>Law 29/2006</u>, of 26 July, on guarantees and <u>rational use of medicines and health products</u>, it is the responsibility of the Spanish Agency for Medicines and Medical Devices to determine when a product should be considered a medicine and to adopt the appropriate measures to guarantee the protection of consumers in the event that this medicine does not meet the established legal requirements.



These measures may include ordering the withdrawal from the market, quarantine or a ban on the marketing of the illegal medicinal product. The AEMPS publishes <u>recalls and</u> <u>information notes on illegal medicines on its website</u>, and always shares them with CELAD through an established notification system.

The regulations, with the aim of protecting citizens' health, also establish that legally authorised medicines must be marketed through the legal channels established for this purpose, and dispensed through authorised pharmacies or pharmacy services in accordance with the provisions of the regulations in force.

The purchase of medicines outside these channels, such as through illegal websites, puts the health of the consumer at risk. In this area, the Agency carries out the tasks of supervision and control, within its sphere of competence, and takes action against websites that illegally sell or offer medicines.

In addition, every four years the AEMPS publishes strategies against counterfeit medicines, one of the main objectives of which is to raise consumer awareness of the risks associated with the consumption of counterfeit and illegal medicines, as well as those dispensed illegally to the public. To achieve this, health authorities carry out information campaigns targeting the general public. Public awareness has proven to be one of the most effective actions to protect the health of the population.

In relation to medical devices that are frequently used for prohibited methods in sport, as stipulated in the Royal Legislative Decree 1/2015, it is considered a very serious infringement the use by a professional of medical devices under conditions and for uses other than those indicated by the manufacturer, or by unqualified or untrained personnel, with risk to the health and safety of persons.

On the other hand, with the approval of Royal Decree 1275/2011, of 16 September, creating the State Agency "Spanish Agency for Medicines and Medical Devices" and approving its Statute, the Technical Inspection Committee is incorporated among the complementary bodies of this Agency (articles 17.j) and 27) and forms an integral part of it as a collegiate body aimed at developing the functions and activities necessary for the coordination and harmonisation of criteria and requirements in terms of inspection and control between the AEMPS and the Autonomous Regions.

The Technical Inspection Committee is the coordinating body for the inspection and control of medicinal products, medical devices, cosmetics and personal hygiene products, and is



responsible for guaranteeing the homogeneity of criteria and actions of the inspection and control services of the AEMPS and the competent bodies of the Autonomous Regions.

Law 17/2011, of 5 July, on food safety and nutrition.

Article 50. Infringements in matters of food safety and nutrition. Article 52. Penalties.

Article 15 of Law 17/2011 sets out the National Plan for Official Control of the Food Chain.

The <u>National Plan for Official Control of the Food Chain</u> describes the official controls carried out in Spain by different competent authorities at the state, regional and local levels, in order to ensure compliance with regulation throughout the food chain, from primary production to points of sale to the final consumer.

The Plan is a tool for the improvement of all existing official control systems. The description of these activities reveals the evidence of solidity of the base upon which food safety and quality is sustained in Spain, and will also signal, through the annual reports of the Plan, those questions to be resolved so that improvement becomes a continuous process.

Royal Decree 1487/2009, of 26 September, on Food Supplements.

Article 9. Information on the marketing of products. Article 11. Penalties.

Food supplements in Spain must be duly notified to the Health Authorities of the competent Autonomous Communities prior to their marketing. Once this notification has been evaluated and after verifying that it complies with Spanish and European legislation, it is included in a Register of Communicated/Notified food products in Spain which can be consulted publicly (<u>https://rgsa-web-aesan.mscbs.es/rgsa/formulario\_producto\_js.jsp</u>). Similarly, food companies notifying food supplements must be registered in the General Health Register of Food and Food Companies (<u>RGSEAA</u>) and must comply with current legislation on the manufacture, import, storage, marketing, etc. of this type of product.

With the aim of protecting human health and being able to manage food risks to the health of consumers, a coordinated food alert system is in place, whose principles of action and operation are based on the provisions of Article 25 of Law 17/2011 on food safety and nutrition and Articles 50 to 52 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law,



establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Within this system, the Spanish Food Safety and Nutrition Agency (AESAN) is the national contact point for the following alert networks:

- Coordinated Rapid Information Exchange System (SCIRI).
- Rapid Alert System for Food and Feed (RASFF).
- International Food Safety Authorities Network (INFOSAN).

These networks allow constant surveillance of any food-related risk or incident that may affect the health of consumers. The fundamental objective of this system is to ensure that the products available to consumers are safe and do not present a risk to their health.

To achieve this objective, the primary basis is the rapid exchange of information between the different competent authorities, food businesses and consumers, thus facilitating appropriate action on food products that could have an impact on consumers' health.

 Order SPI/2136/2011, of 19 July, which establishes the modalities of border control by the pharmaceutical inspection and regulates the Foreign Health Pharmaceutical Inspection Computer System.

On the other hand, it is interesting to note that Pharmaceutical Inspection Services in customs are the public authority in charge of carrying out customs sanitary controls of medicinal products for human use, including their bulk and intermediate products, pharmaceutical raw materials and medical devices. This includes the control of postal parcels, as well as the inspection of baggage when police or civil guard detect the introduction into the country of unusual quantities of substances or medicines or other similar products.

These services facilitate the detection at the border of any attempt by athletes or related persons to import, export or introduce into the country:

- Substances that may pose a risk to the health of athletes and persons involved in sport, including substances prohibited in sport and illegal medicines containing such substances.
- Products containing pharmacologically active substances which may confer on them the legal status of medicinal products, that may present a risk to the health of athletes and persons involved in sport, including substances prohibited in sport.
- Medical devices which are likely to be used by athletes and persons involved in sport for the manipulation of blood and/or blood components, or for any other practice prohibited in sport.



# • Organic Law 10/1995 of 23 November 1995 on the Penal Code.

On 1 January 2016, the Council of Europe Convention on the counterfeiting of medical products and similar offences that pose a threat to public health, also known as the "MEDICRIME Convention", which Spain signed on 8 October 2012 and ratified on 5 August 2013, entered into force.

This treaty against counterfeit medicines and medical devices involves the implementation of an international instrument focused on aspects related to prevention, protection of victims, promotion of national and international cooperation and the inclusion in criminal law of offences related to the counterfeiting of medical devices that pose a threat to health.

Following the signing of the agreement and in close collaboration with the Ministry of Justice, the AEMPS worked for the incorporation of the content of the agreement into Spanish law, which took place through Organic Law 1/2015, of 30 March, amending Organic Law 10/1995, of 23 November, on the Criminal Code.

With this law, an extensive amendment was made to the offences relating to medicines (Articles 361 to 362 quater), which introduced and criminalised new conducts associated with trafficking in medicines and medical devices and increased the penalties.

It is also important to note that the risks arising from the misuse and illicit trafficking of narcotic drugs and psychotropic substances, the importance of ensuring their availability and rational use for medical and scientific purposes, require special action by regulatory authorities in the intervention, control and monitoring of these substances in all fields, from production to consumption.

This action must be coordinated within the framework of constant international cooperation and control guided by identical principles and common objectives. This is how, on the one hand, the United Nations Single Convention on Narcotic Drugs of 1961 (signed by Spain on 27 July 1961 and ratified by Instrument of 3 February 1966) and, on the other, the Convention on Psychotropic Substances of 21 February 1971 (signed by Spain by Instrument of Accession on 2 February 1973) are conceived, both of which are subject to the control of international law.

The 1961 Single Convention on Narcotic Drugs (hereinafter, 1961 U.C.) is amended by the 1972 Protocol of Amendment done at Geneva on 25 March 1972. Spain approves and ratifies the provisions of the Protocol by the Instrument of Ratification of 15 December 1976.



Likewise, in Spain, Organic Law 10/1995 of 23 November 1995 on the Penal Code, Article 368 punishes as crimes: the illicit cultivation, processing and trafficking of toxic drugs, narcotic drugs and psychotropic substances, the illegal possession of these for these purposes, as well as activities that promote, encourage or facilitate their illegal consumption.

However, the mere possession of drugs alone does not constitute a crime as long as it is not intended for the illegal trafficking of narcotics. Organic Law 4/2015 on the Protection of Citizen Security establishes serious or very serious administrative sanctions with fines of 601 to 30,000 euros.

Furthermore, Article 362 quinquies of Organic Law 10/1995 of 23 November 1995 of the Penal Code stipulates as an offence:

1. Those who, without therapeutic justification, prescribe, provide, dispense, supply, administer, offer or facilitate to non-competitive federated athletes, non-federated athletes practising recreational sport, or athletes participating in competitions organised in Spain by sports entities, prohibited pharmacological substances or groups, as well as non-regulatory methods, intended to increase their physical capacities or to modify the results of competitions, which, due to their content, repeated ingestion or other concurrent circumstances, endanger their life or health, shall be punished with a prison sentence of six months to two years, a fine of six to eighteen months and special disqualification from public employment or office, profession or trade, for two to five years.

2. The penalties provided for in the previous section shall be imposed in their upper half when the offence is perpetrated in any of the following circumstances:

- 1. that the victim is a minor.
- 2. deception or intimidation has been used.
- 3. the perpetrator has taken advantage of a relationship of work or professional superiority.



#### **CELAD's Anti-doping Inspectorate**

It is worth highlighting Article 53 of the new Organic Law 11/2021, which addresses the obligation for athletes, teams, and managers to declare, by means of express notification to CELAD, the products likely to give an adverse analytical finding in a doping control that are to be introduced into Spanish territory. CELAD inspectors, ex officio or at the request of the customs authorities, may inspect these kits and other products, in order to verify compliance with the provisions of this Law and the provisions for its development.

One of the important novelties introduced at the national level by the new Organic Law 11/2021 is the preponderant role attributed to the CELAD inspectorate in relation to, among other things, the control and supervision of products, medicines, and nutritional supplements.

The Law states that CELAD is responsible for ensuring compliance with the Law by carrying out the necessary inspections, with suitably qualified and university-trained officials.

In application of this Law and its implementing legislation, CELAD inspectors shall be authorised, in the exercise of their duties, to:

- Enter freely and without prior notification, at any time, in any sports establishment or facility, sports centre, sports service, sports entity, or sporting event.
- To carry out any tests, investigations, or examinations necessary to verify compliance with this regulatory framework.
- Take samples of products or biological samples, in order to verify compliance with the provisions of this regulatory framework and always respect the mandates concerning the protection of personal data.
- Seize medicines and medical devices that have not been notified.
- To carry out as many actions as may be necessary in order to comply with the inspection functions that they perform.

The inspections carried out by CELAD will be carried out by public officials who, in the exercise of their duties, will have the status of agents of the authority and, therefore, will be considered public authorities; for this reason, they will have to be provided with a document accrediting their status, issued by the Director of CELAD. These inspectors will enjoy full technical and functional autonomy in the exercise of their duties and will be guaranteed protection against any kind of violence, coercion, and threat, and independence from any undue influence. The reports drawn up by these inspectors shall have the status of public documents and, unless proven otherwise, shall constitute proof of the facts contained therein.



In those cases in which its Director considers it appropriate, CELAD officials may be assisted by experts, technicians and specialists who are of special interest in the inspection tasks, and their activity will only be limited to assisting and collaborating with the inspecting personnel, under whose orders they will carry out their work.



## 6. PART SIX - TESTING AND THE ANALYSIS OF BIOLOGICAL SAMPLES

## 6.1. Testing and NADO Operational Activities

## 6.1.1 Testing of Athletes

## **General description**

CELAD's doping control department has been certified according to ISO 9001:2015 since 20 February 2019. Its scope of the certification includes:

"The scope of the management system of the CELAD, includes: The performance of doping risk analysis in Spain, preparation of the Test Distribution Plan, monitoring of the development of the planning of controls, management of sampling. Evaluation of the results generated by the analysis of the samples, management of the updating of the biological passport and management of the authorizations for therapeutic use"

For all these processes CELAD has defined processes and performance indicators of these. All procedures have been described in line with international standards and guidelines of the World Anti-doping Agency.

According to this scheme, the sampling process is managed according to a set of operating procedures, including those that have the greatest relevance are the PNT-DCD-01 and the PNT-DCD-03.

In general terms the work is organized according to the following order:

- 1. October of the outgoing year. Based on the data of the development of the TDP of the year, the risk analysis is reviewed.
- 2. November to December. Preparation of the Test Distribution Plan for the coming year.
- 3. Loading into ADAMS of the TDP once it is approved by CELAD management
- 4. Monthly monitoring of compliance with the control distribution plan.

In addition to the controls that are collected within the CELAD TDP, CELAD provides service to any ADO that may request its services acting as a coordinator with a Sampling Company.



## Organization of the sampling.

The entire sampling process, both associated with the samples that are collected within the Test Distribution Plan and outside, orders from other organizations that cover the expense, are carried out through the subcontracting of service providers. To facilitate the competition of several companies and avoid dependence on a single company, Spain has been divided into four balanced geographical areas for sampling, see **Table 1**.

	ZONE A	ZONE B	ZONE C	ZONE D		
	GALICIA	CATALUÑA	CASTILLA LEON	EXTREMADURA		
	ASTURIAS	ARAGON	MADRID	ANDALUCIA		
	CANTABRIA	C. VALENCIANA	CASTILLA LA MANCHA	MELILLA		
	PAIS VASCO	MURCIA	ISLAS CANARIAS			
	LA RIOJA	BALEARES				
	NAVARRA					
age	18,26%	31,28%	29,91%	20,58%		

**Table 1.** Geographical areas for sampling

Currently, the distribution of companies by areas is as follows:

## 1. Within the Test Distribution Plan.

- a. Zone A. Almudena. New hire from 1-10-2022 to 8-3-2023
- b. Zone B. Clearidium. The contract ends on 8-3-2023
- c. Zone C. PWC. New hire from 1-10-2022 to 8-3-2023
- d. Zone D. Clearidium. The contract ends on 8-3-2023

## 2. Outside the Test Distribution Plan.

All Zones are awarded to Ibérica Antidopaje y Salud. The contract ends on July 15, 2023.

It is expected that by the date of 8-3-2023 the Royal Decree of Development of the Organic Law 11/2021, of December 28, on the fight against doping in sport, will be approved, which should allow to introduce some important changes that would affect the taking of samples, including reducing the number of doping control agents that must be present in a control. For all these reasons, work will be done on a distribution plan of areas where the four areas will be maintained, but only to carry out controls in conditions of "In competition", in out of competition it will be a unique area.



In the development of this project during the year 2022 it has been possible to verify that the strategy of dividing Spain is positive, but it has presented several important limitations:

- 1. <u>Out-of-competition controls to the registered group of controls</u>: The mobility of athletes between areas generates a lot of problems of cancelling and activating controls for companies, it is very little operational. Therefore, it is proposed to establish a specific contract only for the Out of Competition.
- 2. <u>Use of electronic forms.</u> Since the beginning of the contracting of Service Providers, July 2015 with PWC, we have been working with electronic forms, this allowed us to greatly reduce errors and with a lot of effort to establish an effective communication channel between the PWC database (MODOC) and the CELAD database (DIOCLES). The entry into 2022 of more companies has meant that this capacity has been lost in three of the four areas for controls within the TDP and all outside the TDP. To solve this situation, we are working on two lines:
  - <u>DCO Central</u>, for all those missions where CELAD is not the Test Authority and if the client agrees.
  - <u>Development of CELAD's own paperless system. (FRONT)</u>. The CELAD Database (DIOCLES) is being developed through its own resources, as well as resources associated with European Resilience Funds an interface via WEB that initially would allow to manage mission orders to order services and integrate into DIOCLES the result of the sampling with all its associated forms.
    - Maintain interaction with PWC. If this company continues to provide its services, and since there is already a communication API, its electronic system for filling out forms is maintained in the sampling.

# 6.1.2 <u>Test Distribution Plan</u>

# **Elaboration of the Test Distribution Plan**

1. Risk assessment

Within the scope of CELAD certification is the annual preparation of a risk analysis study. The risk analysis integrates the determination for the coming year of:

• <u>A determination of the necessary sample size of the TDP based on the country's sports</u> results in the last year and compared to surrounding countries. To obtain this



information, data is extracted from several internationally recognized WEB pages, for example, different sources, including "Greatest Sporting Nation", <u>https://www.greatestsportingnation.com/</u>.

 <u>Determination of the risk index for each sport/sports discipline</u>. For the development of the risk analysis, a series of basic documents from WADA, International Standard for Testing, and Investigations (ISTI), 'Identifying Predictive Factors / Gathering Intelligence' (Section 3) and 'Prioritizing and Planning Effective Testing' (Section 4) parts of WADA's Guidelines for Implementing an Effective Testing Program for further guidance.

The doping risk analysis study also includes the criteria for the individual assessment of athletes who may be integrated into the **Registered Testing Pool (RTP).** 

## **2.** Elaboration of the Test Distribution Plan.

After the preparation of the doping risk assessment, the next process is the preparation of the Test Distribution Plan. In this document, the performance of controls should always be prioritized according to the risk index characterized above. The TDP begins to be developed in November of the outgoing year so that it can be approved in December and uploaded to the databases, DIOCLES and ADAMS.

The steps followed to develop the TDP are:

- 1. Meeting with management to know the budget allocation.
- 2. Assessment of the status of sampling records with service providers
- 3. Distribution of controls by sports / sports disciplines according to the risk index, for this purpose it is assessed:
  - Priority is given to sports/disciplines with the highest risk of doping
  - 55% is dedicated to out-of-competition controls and 45% to competition events
  - In out of competition, at least 3 controls are reserved per athlete member of the registered group of controls.
  - The critical events to be attended are defined "in competition", in general, the national championships.



The development throughout the year of the TDP is carried out monthly. Within the Quality System, the indicators presented in **Figure 2** have been defined.

		OBJETIVO MEJORA: (numero de controles efectuados/controles planificados)% por mes.	Mensual: 6-12% (2021)	8%	3,7%	7,1%	3,8%	3,5%	8,6%	6,2%				5,48%
		erectuados/controles planificadosj% por mes. Acumulado anual	Anual: 57% (2021)	80%	3,70%	11,1%	14,9%	20,4%	28,9%	35,1%				35,10%
		OBJETIVO MEJORA; Suma de las desviaciones observadas mensualmente en los analisis especificos de ESAS y GHRF para cada	ESAS	15%		29,0%	25,0%	25,5%	30,6%	23,4%				23,40%
2022	PLAN DE DISTRIBUCIÓN DE CONTROLES PRC-DCD-003	deporte/disciplina frente al total de controles efectuados al mes %. Acumulado anual	GHRF	5%		7,0%	13,0%	7,8%	16,7%	6,3%			23,40% 6,30% 1,16%	
	TRODED-003	OBJETIVO MEJORA: Porcentaje de controles fuera de España frente al total mensual. Mensual	No hay	1%	4,2%	0,8%	0,5%	0,7%	0,5%	0,4%				1,16%
		OBJETIVO MEJORA: (numero de muestras de ABP	Mensual: 5-10% (2021)	8%	6,3%	11,8%	3,7%	1,4%	11,6%	8,4%				7,20%
		recogidas/muestras planificadas de ABP)%. Por mes. Acumulado anual	Anual: 50% (2021)	70% fin de año	6,3%	18,1%	21,8%	23,1%	31,8%	46,5%				46,50%

Figure 2. Improvement objectives associated with the fulfilment of the TDP.

# **3.** Loading the TDP in ADAMS and DIOCLES.

The TDP is made accessible to WADA by uploading it to ADAMS so that ADAMS NextGen can verify compliance with it, especially the monitoring of specific analyses and compliance with TDSSA, see **Figure 3**.

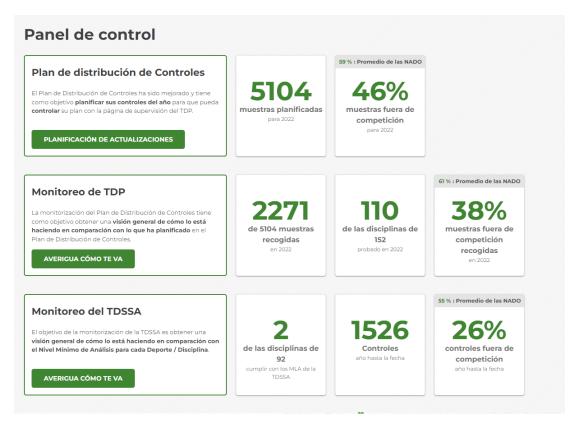


Figure 3. TDP tracking in ADAMS, data extracted, 25-8-2022.





Within the CELAD Database (DIOCLES) the TDP is loaded, in **Figure 4** an example of the follow-up by sport/discipline is shown.

▼ Selección Año															
Año 2022 Clargar Muster (Plan)															
Exportar a Excel															
Arrastre un encabezado	o de columna y póngalo a	qui para agrupar por	ella												
Deporte 🛓 🔷 👻	Disciplina 🗸	Total Planif. 🗸 🗸	Total Realizado 🗸 🗸	EC Planif. 🔷 🗸	EC Realizado 🛛 👻	FC Planif. 🗸 🗸	FC Realizado 🛛 👻	ESAS Planif. 🗸 🗸	ESAS Realizado 🛛 👻	hGH Planif. 🗸 🗸	hGH Realizado 🗸 🗸	GHRF Planif. 🗸 🗸	GHRF Realizado 🗸 🗸	ABP Planif. 🗸 🗸	ABP Realizado
Actividades subacuáticas	Apnea	10	4	10	4	0	0	2	2	0	0	1	1	0	0
Actividades subacuáticas	Buceo de competición	5	8	8	6	0	0	1	1	0	0	1	1	0	0
Aeronáutica	Ala delta y paraperte	4	0	4	0	0	0	0	0	0	0	0	0	0	0
Ajedrez	Ajedrez	4	0	4	0	0	0	0	0	0	0	0	0	0	0
Atletismo	Pruebas combinadas	25	7	18	4	7	3	5	2	5	0	9	4	0	0
Atletismo	Saltos	40	39	30	34	10	5	4	8	7	0	12	5	0	0
Atletismo	Larga Distancia >= 3000m	340	198	204	105	135	93	103	98	10	0	35	74	102	84
Atletismo	Media Distancia 800-1500m	130	77	78	47	52	30	20	20	0	0	27	22	39	35
Atletismo	Velocidad <= 400m	140	55	84	38	50	19	15	5	22	0	43	20	0	0
Atletismo	Lanzamientos	60	34	33	24	27	10	4	0	10	0	19	21	0	0
Bédminton	Bádminton	10	8	7	8	3	0	2	2	0	0	3	2	0	0
Balle deportivo	Balle deportivo	4	0	4	0	0	0	1	0	0	0	1	0	0	0

Figure 4. Follow-up of the TDP in DIOCLES, data extracted, 25-8-2022

## **Sample collection**

## 1. Interaction with Service providers for sample collection

The planned sampling within the TDP is carried out by several companies providing the service, depending on these the systematics that are followed for the communication of the control missions varies, in summary:

## Inside the TDP:

- a. AREA A. Almudena Moreno.
  - Communication of missions with their controls. Through ADAMS. It does not exist in ADAMS as a service provider, CELAD must be indicated as ETM.
  - Submission of Forms by ETM. Via email. They do not load into ADAMS.
  - Sending paper forms by courier, every 10 days.
  - Paperless, does not exist.

## b. AREA B + D. CLEARIDIUM

- · Communication of missions with their controls. Through ADAMS.
- Submission of Forms by ETM. Via TEAMS platform. Loading in ADAMS only controls collected Out of Competition.
- Sending paper forms by courier, every 10 days.
- Paperless, does not exist.



- c. AREA C. PWC
  - · Communication of missions with their controls. Through DIOCLES.
  - Submission of Forms by ETM. Via API MODOC-DIOCLES. Loading in ADAMS only controls collected Out of Competition.
  - Sending paper forms by courier, every 10 days.
  - Paperless, implemented since 2016.

# OUTSIDE THE TDP

- a. AREA A-B-C and D. Ibérica Antidopaje y Salud, IADS.
  - · Communication of missions with their controls. Through ADAMS and ODOO.
  - Submission of Forms by ETM. Via email. They do not load into ADAMS.
  - Sending paper forms by courier, every 10 days.
  - · Paperless, pending implementation of DCO Central.

## 2. Service Providers activity tracking.

Within the doping control department, the work is organized according to the organizational chart in **Figure 5**:

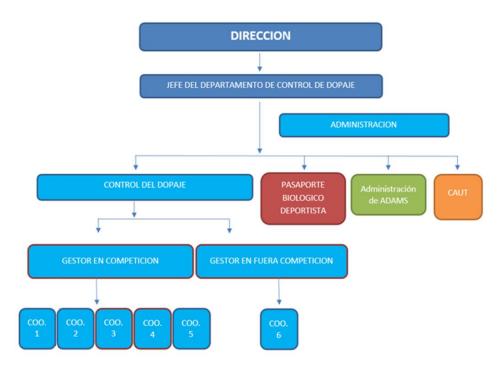


Figure 5. Organization chart of the Doping Control Department



Based on the organizational chart it can be verified that the department divides the controls into "In competition" and "Out of Competition". In each work area, there is a person in charge of coordination and a series of people in charge of the planning and monitoring of the controls. Among the tasks of these coordinators are:

- Contribute to the definition of the TDP.
- Organize controls and information loading for the Service Providers
- Carry out the loading in Databases of the Controls.
- Review the correct performance of the controls. Registration of inconsistencies for the assessment of the Service Providers.

## 6.1.3. Testing of overseas athletes

## Foreign athletes residing in Spain.

CELAD has a contract with a Sampling Company that is responsible for sampling foreign ADOs that carry out orders. In CELAD there is a web page (English / Spanish) that allows you to easily carry out the order.

Once the order has been received, CELAD evaluates the ADO, whether it has delinquency, and if not, sends you a quote that may also include the analysis of the samples in a WADA accredited laboratory, in general Madrid. When the budget is returned signed, following the instructions of the CELAD Control Authority, the order is communicated to the sampling company. In turn, CELAD will also oversee creating the mission in ADAMS, and once the controls have been carried out, upload them to ADAMS so that they are accessible to the client.

## Spanish athletes who reside/train outside of Spain.

At this point, we are working on establishing some type of contract with the sampling companies that allows the taking of samples outside Spain without being incompatible with the Spanish Regulations in force. It is pending to modify the Royal Decree of Development of the Organic Law Anti-doping, which will allow it to be less restrictive and facilitate the taking of samples.



# 6.1.4. Testing in Major Sport Events.

The coordinators extract throughout the year information from the WEB pages of the Spanish Sports Federations the information of the concentrations prior to sporting events of international importance, as well as from the web page of the Higher Sports Council it is possible to extract the dates of the most important competitions for each sport, with this controls are programmed prior to the events in the concentrations, or if they are athletes integrated into the registered group of controls, controls adjusted to their ADAMS location.

# 6.1.5. <u>The role of the NADO in relation to anti-doping rules adopted by sports</u> <u>organisations within the Host Party</u>

No rules are drawn up for other federations and/or organizers of sporting events, nor does it supervise.

## 6.1.6 Reciprocal Testing

CELAD does not need the signing of agreements that regularize the management of controls in Spain for ADOs from other countries or controls on Spanish athletes outside our country. The system that has been implemented for a few years is based on the provision of the service by paying the costs of the service in Spain. Prices are public through publication in the Official State Bulletin.

Regarding the controls outside Spain to Spanish athletes, there are two options, sometimes they are requested to International Federations in exchange for controls in Spain, or by requesting a budget to the NADOs, and that once the expenditure file is approved, it allows the payment of the service. The whole process is carried out in the ADAMS environment, but recently CELAD has begun to use Central DCO.

## 6.2. Laboratories and Analysis

6.2.1. <u>Analysis of biological samples provided by athletes in WADA-accredited</u> <u>laboratories</u>

There is no exception under which samples that CELAD collects as a supervisory authority or that coordinates sampling for a third party are sent to a laboratory not accredited by WADA. CELAD only provides service in the Anti-Doping environment and therefore only employs the services of WADA-accredited laboratories. In general, the Madrid Laboratory is always used,



but when the client requests it, the samples can be sent to another WADA accredited laboratory.

6.2.2. WADA-accredited laboratories in Spain/ relationship with the NADO/sports organisations/ Athlete Passport Management Unit (APMU)

## WADA-accredited laboratories in Spain

Spain is one of the few countries which counts with two WADA-accredited laboratories in its territory:

Madrid Anti-Doping Laboratory (DCL-MAD)

Currently integrated as an independent department within CELAD, although it is expected that within a short time it will be integrated into the Carlos III Health Institute. It will therefore be Organic and Budgetarily totally independent of CELAD. It will be established when this occurs an agreement/contract for the shipment of samples to this laboratory. The Laboratory has no relationship with the Spanish sports federations.

The analysis of samples collected by CELAD as a Testing Authority within the annual national testing program are almost in their totality analysed in Madrid Anti-Doping Laboratory (DCL-MAD). For DCL-MAD, the doping control samples collected by CELAD represent around 50-55% of its annual activity.

Catalonian Anti-doping Laboratory (DCL-CAT)

Currently integrated as an independent department within the Fundació Institut Hospital del Mar d'Investigacions Mèdiques (IMIM Foundation). Currently, it does not routinely perform sample analysis for CELAD. The <u>Athlete Passport Management Unit</u> (APMU) of this laboratory is contracted by CELAD to carry out the assessment of the biological passports of which CELAD is the custodian. The Laboratory has no relationship with the Spanish sports federations.

# Madrid Anti-Doping Laboratory (DCL-MAD)

DCL-MAD started its activities in 1969, analysing samples from international competitions in Athletics and Cycling, after achieving the homologation of the corresponding International Federations (IAAF and UCI) for performing such analysis.

MINISTERIO DE CULTURA Y DEPORTE

COMISIÓN ESPAÑOLA PARA LA LUCHA ANTIDOPAJE EN EL DEPORTE



In 1983, DCL-MAD achieved the accreditation of the International Olympic Committee for performing control doping analysis in sport. This accreditation was maintained since then, although in 2003 it was substituted by the WADA accreditation.

In 2001, DCL-MAD obtained the accreditation for quality assessment of EN 45001:1989, but modified subsequently to the ISO/IEC 17025. This accreditation was provided by Spanish National Accreditation Body (Entidad Nacional de Acreditación-ENAC) and includes all the requirements that assay laboratories must comply with to demonstrate that they are technically competent, able to produce technically valid results and dispose of a Quality Management System. This accreditation has been kept over the years.

In this more than 50 years of operation, the DCL-MAD has analysed more than 250.000 doping control samples collected in and out of competition in Spain and other countries. In fact, DCL-MAD has provided its services for doping control analysis to different NADOS like Autoridade Antidopaje de Portugal (Portugal NADO), Comisión Nacional de Control del Dopaje de Chile (Chile NADO) and nowadays it is the main provider of services for Argentina and Uruguay NADOS (Comisión Nacional Antidopaje de Argentina and Organizacion Nacional Antidopaje de Uruguay). In addition, other punctual analysis services are provided to other European NADOS, like the Agence Française de Lutte contre le Dopage, Nationale Anti-Doping Agentur Deutschland and others. The samples collected by other NADO different from the Spanish NADO represent around 16-20% of the total samples annually analysed in DCL-M.

Moreover, DCL-MAD is also used by several International Federations (World Athletics - Athletics Integrity Unit, World Triathlon, Union Cycliste Internationale, Fédération Internationale de Football Association, Union Eurepéenne des Associations de Football, International Tennis Federation, etc). In fact, around 31% of samples annually analysed in DCL-MAD are collected by International Federations.

The DCL-MAD has analysed samples collected in World Championships (Athletics, Basketball, Cyclist, Football, Gymnastics, Fencing, Swimming, Canoeing, Taekwondo, Archery, Sailing, among others), in regional Championships (Pan Americans, Europeans, Mediterranean, America's Cups), University Championships, International Leagues, in addition to the analysis of other samples collected during important international competitions like for example Vuelta Ciclista a España.



# **Catalonian Antidoping Laboratory (DCL-CAT)**

The DCL-CAT, formerly Barcelona Antidoping Laboratory, is a WADA-accredited Anti-doping Laboratory. The Laboratory received the first accreditation to perform anti-doping analytical tests on athletes in 1985 by the International Olympic Committee and holds WADA accreditation since 2004.

The DCL-CAT belongs to the Neurosciences Research Program at Fundació IMIM (Hospital del Mar Medical Research Institute) in Barcelona (<u>www.imim.es</u>) The DCL-CAT depends administratively on Fundació IMIM and it is independent of the organizations that provide it with biological samples for analysis.

The DCL-CAT analyses samples collected at competitions (in-competition tests) or during training periods (out-of-competition tests), at the request of national, foreign, and international sports organizations, since 1985.

The DCL-CAT hosts the Catalonian Antidoping Laboratory-APMU (Athlete Passport Management Unit) which was approved by WADA Executive Committee in September 2019 to start operation in January 2020. The APMU has agreements with different National Antidoping Organizations and International Federations for the management of steroidal and hematological modules of the athlete's biological passport and, among them, offers APMU services to CELAD (A.E. Comisión Española para la Lucha Antidopaje en el Deporte) since January 2022.

## 6.2.3. Governance, independence, and impartiality

## Madrid Anti-Doping Laboratory

In its origins, the DCL-MAD was linked to Supreme Council for Sports, but in 2008 with the creation of the State Anti-doping Agency (AEA), which was the organization that assumed the competences related to the NADOs in Spain, DCL-MAD was transferred to the Doping Control of Prevention Department of this Agency.

In 2013, the State Anti-doping Agency (AEA) was transformed into the Spanish Agency for Health Protection in Sport (AEPSAD), and with the aim of improving impartiality and independence, the DCL-MAD was converted into an independent department unaffiliated with the Administrative Structure of AEPSAD and linked directly to the AEPSAD Director. Currently, the governance of DCL-MAD is in a period of transition.



In the first place, with the entry into force of International Standards for Laboratories of WADA on January 2021, the administrative dependence of the DCL-MAD from the Spanish NADO has led to the non-compliment of the Laboratory with Article 4.4.2.4 of this International Standard.

Supreme Council for Sports, Spanish NADO, and DLC-MAD have been working to solve this situation.

On April 2022 a Framework Agreement between Spanish NADO, Carlos III Health Institute (ISCIII), and Supreme Council for Sports was signed to transfer the DCL-MAD from Spanish NADO (depending on Ministry of Culture and Sport) to Carlos III Health Institute (ISCIII), depending from Ministry of Science and Innovation.

ISCIII is an important research organization in Spain, not related to Sports, dedicated to the improvement of the citizen's health and the fight against illness, administratively depending on the Ministry of Science and linked in part of its activities to the Ministry of Health.

Due to the procedure of changing the administrative dependence of the DCL-MAD from one institution to another requires previous agreements and changes of Law, a grant extension of the deadline for the compliance of this specific requirement was requested from WADA.

WADA accepted such grant extension, until 24th October 2022, but with the condition of DCL-MAD reported monthly about the updates in the procedure.

On the other hand, the approval on 28th December 2021 of Law 11/2021 of Fight Against Doping in Sport, has transformed the old Spanish Agency for Health Protection in Sport (AEPSAD) into the CELAD. The structure of this new organization must be developed in a Law of Structure and Bylaw, and this new structure shall not include the DCL-MAD. After approval of this Law, DLC-MAD will be directly linked to the General Sub direction of Applied Services, Training, and Research, which is one of the departments of ISCCIII, that will eliminate any possible dependence of the DCL-MAD from the organizations that provide it with biological samples for analysis.

During the interim period, DCL-MAD is still and independent department directly linked to Spanish NADO (nowadays CELAD) Direction. Although in this structure DCL-MAD depends administratively from CELAD, it has been fully independent and impartial in its operation. This independent operation has been based on the next:



## DCL-MAD Director.

DCL-MAD Director was appointed by the Board of Government at proposal of the Director of Spanish NADO, but previous to that, the Director of AEPSAD contacted WADA, in the terms of ISL, to propose his candidate and to get WADA approval for such appointment.

DCL-MAD Director operates with absolute independence and total objectivity, not reporting about the ordinary affairs, related to the operational activities of the Laboratory, to anyone in the Organization, neither the Director of CELAD.

That includes any information regarding the analysis of samples, results of EQAs samples, results of WADA and ISO/IEC 17025 audit, ISO/IEC 17025 Management Reviews, but also includes organization of laboratory staff, distribution of task and responsibilities between laboratory staff, purchases performed in the lab for routinely analysis and for implementation of new methods, the decision on the implementation of new methodologies or in the analysis strategy, the decision on researches and projects in which Laboratory participates, the customers to whom the Laboratory provide its services, the feedback that Laboratory receives from customers, the internal objectives established annually in the Laboratory.

DCL-MAD Director is evaluated in the performance of her duties and responsibilities, based on criteria of efficacy, efficiency, law compliment, and responsibility in her management and control in the compliment of the objectives.

# DCL-MAD Budget.

Due DCL-MAD is part of a Public Organization, its main source of income is obtained from the State Budget. Part of the State Budget that Spanish NADO received from the Government is directly allocated to the Laboratory, and it is the Laboratory Director who proposed how to use this budget.

However, the DCL-MAD can invoice the testing services performed to other customers different from the Spanish Anti-Doping Agency (CELAD).

Therefore the source of DCL-MAD income can be summarized in: 84% Government Allocated Budget (40% cost of staff + 44% purchases and services) + 16% testing services.



Due to the DCL-MAD budget is mainly obtained via the State Budget, the Laboratory's procurement and approval process must comply with Law 9/2017, 8th November on Public Sector Contracts.

In order to guarantee the fulfilment of such Law, it is the General Secretary Department who performed the procedure for purchasing, but always at the Laboratory Director proposal.

# • DCL-MAD staff.

Almost all the Laboratory's staff are civil servants (90%) with a fixed-term contract allocated to the Laboratory (which means, they cannot be laid off and their salaries are fixed and stipulated by State General Administration).

# DCL-MAD facilities.

Laboratory facilities are placed in a different location in Madrid, from the rest of the departments, including the Direction of CELAD.

# **Catalonian Antidoping Laboratory**

The DCL-CAT has total operational autonomy (sample analytical testing, reporting of results, allocation of the budget, procurement of equipment and other resources, personnel management, and research performed by the Laboratory).

The DCL-CAT analyzes samples and reports results in conformity with the WADA International Standard for Laboratories.

The DCL-CAT only communicates regarding analytical testing and/or reporting of results to the relevant Testing Authority or Results Management Authority (if different) or WADA.

The DCL-CAT has the support of Fundació IMIM for human resources activities and financial and administrative duties.

# DCL-CAT Budget.

The funding of the DCL-CAT is as follows: anti-doping analyses and APMU services (72%), Catalonian Government (Secretaria d'Esports I de l'Activitat Física) (20%), and research grants (8%).



# 6.2.4. Full and efficient use of the analytical capacities/ evolution with the strengthening of the existing analytical methods/ new methodologies.

# **Madrid Anti-Doping Laboratory**

The DCL-MAD is staffed by multidisciplinary professionals, highly specialized and trained, with senior scientists (with more than 15 years in doping control analysis) composed of around 25 workers.

The DCL-MAD is equipped with a wide game of analytical instruments, able to develop the numerous analytical methodologies required in doping control analysis, and able to fulfil with the exhaustive technical requirements set by WADA. DCL-MAD has a number of available instruments enough to allow the analysis of around 7000 samples per year.

The DCL-MAD has the politics and the compromise of continuous improvement and updating of its analytical methodologies and service portfolio. During the last two years, DCL-MAD has reduced the limits of detection and limits of identification on most of the prohibited substances and/or markers of the prohibited substances, the method of detection and confirmation of erythropoietin (EPO) and other EPO-receptor agonists (ERAs) has been revalidated to improve selectivity and sensitivity (according to WADA new requirements), the accreditation scope has been extended to include new prohibited substances and new better markers or additional markers of the use or the administration of prohibited substances. DLC-MAD has implemented some WADA non-mandatory analytical methods, like the analysis or LH or the analysis of growth hormone by the biomarkers assay. In addition, DLC-MAD has the objective of developing and validate a method for analysis of other non-mandatory methodologies like the analysis of growth hormone-releasing hormone (GHRH) and the analysis of ester of steroids in Dry-Blood-Spot samples (DBS).

## **Catalonian Antidoping Laboratory**

The DCL-CAT develops an important research activity to contribute to the progress of doping control in the sport, to ensure fair sport, and to protect the health of athletes and the general population.

The DCL-CAT has a total commitment to the development and implementation of new methodologies to fight against doping in sports.

The DCL-CAT has ongoing funded research projects in the following research lines: discrimination between prohibited and allowed use of glucocorticoids in sport; detection of



endogenous anabolic androgenic steroids misuse; confounding factors of the athlete biological passport (steroidal and hematological modules); and analysis of doping agents in dried blood spots (DBS).

# 6.3. Long Term Storage

According to the study of risk analysis for those controls that have been defined as very high risk of doping and for those athletes of the Registered Group of Controls who in their individual assessment reach the highest value, the samples must be stored by prolonged procedure with the idea of carrying out retrospective analysis of the samples, when:

- Depending on the evolution of the points of the Biological Passport of the Athlete, it is appropriate to carry out additional analysis of some of the points.
- According to intelligence associated with very high performances in certain sporting events. Or because of a complaint.
- The implementation of some novel analysis methodology in the laboratory.

Retrospective analysis is implemented in CELAD.





# 7. PART SEVEN - EDUCATION AND RESEARCH

# 7.1. EDUCACIÓN

CELAD's Education and Research Department is currently composed of 5 people. Following the entry into force of the WADA International Education Standard on January 1st, 2021, all educational actions are in line with the standard, from the preparation of an Education Plan to the division of education into target groups based on age and/or competitive level. Of course, this document is available.

## 7.1.1 Levels of education and training regarding anti-doping

In line with the sports structure of our country, the target groups to which we mainly direct our actions are:

- Athletes and support personnel from national federations
- Athletes and support personnel from regional federations
- Athletes and support personnel from clubs and associations
- Undergraduate students from the Universities of Physical Activity and Sport Sciences.

The general educational competencies in Spain fall under the umbrella of the regional authorities. Therefore, the following groups are out of our scope of action:

School (elementary, primary, and secondary) students, and academic CV.

## 7.1.2. Legislative measures on anti-doping education

The project of the Royal Decree that will develop the dispositions contained in the <u>Organic Law</u> <u>11/2021</u> contains specific provisions concerning the collaboration between the CELAD and different entities in anti-doping educative programs.

The CELAD will plan, set up, evaluate and promote anti-doping educational programs. The CELAD will coordinate the execution of those programs in collaboration with Autonomous Regions, National Sports Federations, and other entities included in article 3.2 d) of the Organic Law 11/2021, the Spanish Olympic Committee, the Spanish Paralympic Committee, and other public or private entities of sport, health, and educational scope.



Additionally, the project of the Royal Decree establishes that sport clubs, sport federations, sport associations, entities included in article 3.2 d) of the Organic Law 11/2021, and health entities will have to collaborate in setting up the educational programs and are obliged to facilitate with due diligence the information requested by the Spanish Anti-doping NADO.

### 7.1.3 **Practical and operational aspects of anti-doping education**

In Spain, we deliver anti-doping education with different institutions through collaboration, commitment, and insistence. A significant percentage of National Federations have already integrated our subject matter into their activities and therefore, they make our work much easier.

As far as Universities and Club Associations are concerned, collaboration is based on agreements reached based on the interest that anti-doping education arouses among their members.

Since 2015 the Education and Research Department has been developing its educational programs, in partnering with national, private, and public institutions.

Current programs:

### Doping, what you should know:

Program designed for athletes and coaches from sports federations that are included in the art. 18.2 from the World Anti-Doping Code. The target groups for the <u>online</u> and face-to-face sessions are athletes from the registered testing pool; athletes returning from a sanction; international level athletes and coaches; over 18 national athletes and coaches; athletes between 16 and 18, and their support personnel; athletes between 12 and 15, and their support personnel.

Values and clean sport: in addition to the main "principles and values" section, we have included a broad psychology-based course to make athletes and their supporting environment capable of making responsible decisions.

### <u>Life without cheating:</u>

Program focused on undergraduate sport science students. It covers general doping concepts, psychological-related issues in doping, and a personal and social responsibility section (adapted from Hellison's model). Those who attend this 30-hours-course get 1 ECTS (free elective credit).



COMISIÓN ESPAÑOLA PARA LA LUCHA ANTIDOPAJE EN EL DEPORTE



### Sportplus:

Sportplus is an educational program in doping prevention, created by CELAD, and oriented to the integral development of young athletes. Its general objective is to educate and train in the prevention and fight against doping by providing professional tools to the athlete's environment.

Sport Plus is aimed at support staff (coaches, physical trainers, coordinators, parents...) of sports clubs that work with athletes of any sport discipline aged between 13 and 18 years old.

The program is carried out together with ACEDYR (Association of Sports and Recreational Clubs and Entities) and other associations to broaden the boundaries of anti-doping education, reaching a much larger population.

### <u>University expert in doping prevention.</u>

The Department of Education and Scientific Research together with the Department of Doping Control of the CELAD and the Catholic University of Murcia (UCAM), have developed the university degree "University Expert in Doping Prevention" with a teaching load of 20 ECTS credits.

This degree offers the necessary training to know in depth the meaning of doping, its health and legal consequences, the methods to fight against doping, and the prevention strategies.

As part of the training for the title of "University expert in doping prevention", the course of doping control agent is included so that the qualification of Doping Control Agent of the CELAD is obtained once the training is finished, allowing them to work as DCOs.

Our programs are configured to be developed both in person and online. Due to the Covid-19 pandemic, most of them have been developed virtually without having recovered normality in terms of presence at the moment. All programs are hosted on our online platform to facilitate their implementation and are accompanied by downloadable content guides and interactive infographics so that they can be integrated into the websites of the national federations.

Additionally, on the CELAD website, there is a tab dedicated to education where our activities are explained and our materials are shown.



We also rely our education programs on 12 educators from which some are former elite Spanish athletes and others still competing at an elite level. Their role is to carry out educational actions following the requirements listed in the 2021 WADA Guide and the International Standard for Education. All educators taking part in our programs have received a 30-hourseducation course based on the general anti-doping concepts gathered in (Art.18.2 WAC), doping-related psychological issues, values, and fair play, and the personal and social responsibility model from Hellison. They are also given updating workshops every 2 months.

Their collaboration is key due to their commitment to promoting fair play values within training centers, federations, clubs, and several regional institutions. Each educator has been named the official educator for CELAD's Education Department by the Agency's director resolution.

## 7.2. **RESEARCH**

### 7.2.1 <u>Testing and research</u>

### Implementation of the use of the Doping Prevalence Survey

CELAD is collaborating with Dr. Andrea Petrozci as the leader of the WADA working group on the implementation of a survey measuring the prevalence of doping in sport. The collaboration work began in November 2020. In May 2021, the survey was opened for the first time in online mode for more than 3000 Spanish athletes of national and / or international competitive level to complete it. The survey was closed in September 2021. In April 2022 the results were presented at the WADA-ADOs international congress that took place in Lausanne. The scientific publication that will review these data is still pending.

During the development of the Spanish Outdoor Athletics Championships, (Nerja 23-26 June 2022), in collaboration with the Francisco de Vitoria University (UFV) and Rey Juan Carlos University (URJC), data collection was carried out in face-to-face mode for the prevalence survey. If the 754 participants in the event were collected more than 350 valid surveys, currently the data are being processed by KU, and it is expected that by mid-September 2022 the data will be available.



#### Monitoring and assessment of anti-doping statistics.

In collaboration with Camilo José Cela University (UCJC), UFV, and URJC, CELAD periodically carries out descriptive studies on the evolution of doping to obtain interest that can be applied to risk analysis and therefore define the TDP. As a result of this work, more than 10 peer review publications were made.

### Use of sampling systems in Dry-Blood-Spot samples (DBS) support

This is a new line of work that aims to increase the deterrent power and effectiveness of CELAD's anti-doping program. The use of blood sample collection systems in the form of a stain on paper allows, among other things, to speed up the sampling process, and to carry out the blood collection in a simpler way and without the conservation limitations related to temperature. All this makes this new type of support in the future of great interest.

CELAD has currently started the implementation project, which will consist of:

- Acquisition of 500 Hemaxis plates for DBS sampling. Training of Doping Control Agents by the manufacturer. They are the suppliers of the kits that were used by UCI for the detection of Tramadol use using DBS.
- Design of the kit sealing system. A sealing system of 250 kits will be implemented for the 500 Hemaxis plates.
- Collection of 250 controls. A sampling company will be hired for which Control Agents will be trained to carry out the collection using DBS. 125 samples will be in amateur events only with DBS and another 125 combined with urine in a national sports event, scheduled in November 2022 and February 2023.
- Analysis of 250 samples in the doping control laboratory of Catalonia. Of these 125 will be collected in sporting events of low competitive level to evaluate the performance of the kits, the capacity of the Control Agents, and collect the impressions of the athletes. Subsequently, with all this information processed, 125 anti-doping controls with urine and DBS will be carried out in national sporting events to make a comparison between the results of both matrices.

# **Development of methodology for the detection of doping substances in nutritional supplements**

As a result of the results obtained in the survey on nutritional habits of elite athletes in Spain, it was decided to carry out a sampling among the most consumed products to determine the risk that athletes could suffer with the intake of supplements that were contaminated.



In September 2018 the purchase of all selected products was concluded. The UCAM in collaboration with the Doping Control Laboratory of Madrid developed a detection methodology that based on the use of liquid chromatography systems coupled with time-of-flight mass spectrometry would allow an analysis of all these products.

At present the method of analysis is finalized, and the products analysed, pending an assessment of the results.

Publications made by the group and linked to this development are:

- Validation of a questionnaire to study the prevalence of nutritional supplements used by elite Spanish athletes. M Aguilar-Navarro, J Muñoz-Guerra, MDM Plata, J Del Coso. Nutricion hospitalaria 35 (6), 1366-1371. 2018
- <u>Gender differences in prevalence and patterns of dietary supplement use in elite athletes.</u> M Aguilar-Navarro, G Baltazar-Martins, D Brito de Souza, J Muñoz-Guerra. Research Quarterly for Exercise and Sport, 1-10. 2020

### Study about hematological parameters evolution

From 2016 to 2019 CELAD has carried out more than 3000 controls where Athlete Biological Passport Haematological Module (ABP-HM) samples are included.

During the year 2020, a descriptive statistical study of the data was carried out, in such a way that it was intended to assess the hypothesis of whether the implementation of the ABP-HM program in Spain had led to some type of change trend that could be reflected in the evolution of the parameters.

On the dependent variable, reticulocyte value and haemoglobin value were studied independent variables such as sampling time, time of year, sport, sex, and type of discipline.

From the study of the data in a global and interindividual way, it was possible to verify that there was a certain tendency, however, to determine the need to expand the amount of data with the information of period 20-22 and to carry out an intra-individual study.

In collaboration with UFV and URJC, we are working on this study.



#### FRONT development, interaction with ADAMS, Boots integration

As it has been indicated in this report, DIOCLES is the CELAD database. At present, its functionality is complete, and, using the experience gained with this platform developed by CELAD itself, work is going to be done on a WEB version of DIOCLES that should allow interaction with the platform of third parties outside of CELAD. The development project involves a significant cost and is being financed by European resilience funds. In general, the hiccups that must be achieved by the end of 2024.

### **Project Understanding and promoting Whistleblowing on Doping irregularities in the EU (Win-Dop)**

CELAD is collaborating in this project with the following organizations; Dr. John Toner and Professor Adam R. Nicholls (University of Hull, UK), Research Assistant: Dr. Lucas Fairs (University of Hull, UK), Collaborating Partners; Aristotle University of Thessaloniki (Greece), Mary Immaculate College (Ireland) the National University of Physical Education and Sports Bucharest, Romania (UNEFS; Romania), The International Council of Sport Science and Physical Education (ICSSPE; Germany), KEA Fair Play Code Hellas (Greece), Anti-Doping Agency of Serbia (ADAS; Serbia) Agenția Națională Anti-Doping Romania/Romanian National Anti-doping Agency (ANAD; Romania).

### 7.2.2 Laboratory lines of research

# Hyphenating SUPRAS and LC-MS-MS for high-throughput universal testing substances in urine

Developed by (PI) Soledad Rubio, Ana Ballesteros-Gómez, Eloy Girela, and Gloria Muñoz from the Analytical Chemistry Department, University of Cordoba, and the Doping Control Laboratory of Madrid. Research project funded by Partnership for Clean Competition (PCC).

Publications of this research:

 <u>A comprehensive study on the performance of different retention mechanisms in sport</u> <u>drug testing by liquid chromatography tandem mass spectrometry.</u>
 S. González-Rubio, A.M. Ballesteros-Gómez, D. Carreras, G. Muñoz, S. Rubio Journal of Chromatography, B, Analytical technologies in the biomedical life sciences, 2021 Jul; 1178:122821. doi: 10.1016/j.jchromb.2021.122821



<u>Cubosomic Supramolecular Solvents: Synthesis, Characterization, and Potential for High-Throughput Multiclass Testing of Banned Substances in Urine.</u>
 S. González-Rubio, A.M. Ballesteros-Gómez, G. Muñoz, S. Rubio
 Analytical Chemistry 94(9); February 2022. doi:10.1021/acs.analchem.2c00082

# Establish the Athlete Internal Metabolic Reference by the Isotopic Signature or Isotopic Fingerprint of $\delta$ 13C values

Developed by (PI) Rodrigo Aguilera, Soledad Vargas-García Tenorio, Gloria Muñoz, Joao Ruivo from the Laboratório de Análises de Dopagem de Lisboa, and the Doping Control Laboratory of Madrid.

### 7.2.2 Education Research

**Evaluation of the Spanish NADO's Educational Interventions among Elite Athletes, Coaches, and Sports Sciences Students** 

Research Project funded by the World Anti-Doping Agency, of CELAD in collaboration with the European University of Madrid (UEM). It is based on the evaluation and study of the effectiveness of CELAD's educational programs. We are currently finalizing the project.

This project will allow us to optimize our programs to be more participant-centered and, potentially, more effective.

The main objective of this research project is to evaluate the effectiveness of current educational interventions carried out by CELAD and subsequently improve and re-evaluate these interventions.

This research takes part in current efforts to find the best possible theoretical framework and intervention delivery for anti-doping educational programs, which are one of the key instruments in a succeeding anti-doping policy as stated by WADA.



### 8. PART EIGHT - DISCIPLINARY MEASURES

# 8.1. DISCIPLINARY AND APPEAL PROCEDURES /HEARING BODY AND ITS OPERATIONAL INDEPENDENCE

The <u>Organic Law 11/2021</u> in its Title II articles 19 to 49 establishes the rules of the sanctioning proceeding.

Specifically, article 46 establishes that the Anti-doping Sanctioning Committee is a collegiate body that acts independently as it cannot receive orders or instructions from anybody in the development of its task. It is composed of 7 persons that will be appointed, previously proposed by the Director of the CELAD, by de Steering Committee of the CELAD for 4 years. Four of the seven members will be elected between prestigious jurists in sports law and three from prestigious professionals in scientific, medical, or sports fields with specific knowledge in anti-doping matters.

The members of the Anti-doping Sanctioning Committee will be irremovable during their mandate and they will act with plain autonomy and independence in the exercising of their duty. The president of the Anti-doping Sanctioning Committee will be appointed by the Steering Committee of the CELAD between their members and proposed by them. As well, one of the members will be appointed as Secretary of the Committee.

The mandate of the members of the Anti-doping Sanctioning Committee will be for four years, being able to be reelected only for a new mandate. The renewal of the members will be made each two years partially.

The Anti-doping Sanctioning Committee is the competent body to resolve the sanctioning proceedings regarding the infractions relating to doping actions as foreseen in the Organic Law 11/2021.

Against the sanctioning resolutions, the athlete will be able to apply before the Anti-doping Sanctioning Committee through a special administrative appeal during a period of a month since the notification of the Sanctioning resolution. There are also legitimate to appeal the International Sport Federation, the Director of the CELAD, the World Anti-doping Agency and the International Olympic Committee, and the International Paralympic Committee.

Against the resolution of the anti-doping special administrative appeal, the athlete will be able to appeal before the contentious-administrative jurisdiction during a period of two months. There are also legitimate appeals to the International Sport Federation, the Director of the



CELAD, the World Anti-doping Agency, the International Olympic Committee, and the International Paralympic Committee.

The Sanctioning resolutions ordered by the Anti-doping Sanctioning Committee relating to an international athlete or ordered in an international competition framework will also be able, alternatively, to be appealed according to the proceeding foreseen in the World Anti-doping Code or international federation.

### 8.2. DISCIPLINARY MEASURES ESTABLISHED FOR ATHLETE SUPPORT PERSONNEL

According to the Anti-Doping Convention of the Council of Europe, the <u>Organic Law 11/2021</u> provides sanctions against those who are associated with or involved in doping violations.

Specifically, article 20 of the <u>Organic Law 11/2021</u> establishes that the following actions will be considered infractions in doping matters:

*d)* To help, incite, contribute, instigate, conspire, cover up or any other type of collaboration in the commission of any of the infractions foresee in this article.

n) The reception of services related to sports or any type of advising, training or collaboration or establishing or maintaining any type of professional relationship, including representation, remunerated or not, with any person who has been suspended by the commission of any doping infraction or condemned by a doping offense in Spain or out of Spain or professional or disciplinary sanctioned because of facts that constitute doping infractions.

Article 23 establishes the sanctions to the athlete support personnel consisting of the ineligibility for the sanitary or professional functions linked to athletes, entities, clubs, teams, federations, or sports establishments for a period of four years. When the infractions were committed with non-specific substances and involved protected persons the ineligibility could be definitive.

## 8.3. MUTUAL RECOGNITION OF SANCTIONS

Article 30 of the <u>Organic Law 11/2021</u> establishes that any sanctioning resolution ordered by anti-doping authorities of other States, sports federations, or international competent bodies or arbitral courts, when acting as appealing concerning the decisions of international federations or the World Anti-doping Agency, will be immediately recognized and thoroughly applicable in Spain in the terms fixed in the World Anti-doping Code.



The CELAD will be in charge of proceeding to the recognition of other States sanctioning resolutions by its own initiative or at the request of athletes if the resolutions do not contravene fundamental rights or public order.



# 9. PART NINE - INTERNATIONAL CO-OPERATION AND PROVISION OF INFORMATION

The collaboration and international cooperation of CELAD with other organizations, in the prevention and fight against doping, has been one of its priorities since its creation.

This work is integrated into the International Relations and Cooperation Area, which is the specific area responsible for the coordination of relations, cooperation and collaboration activities that are developed in CELAD at the international level.

CELAD's international presence in the last years, thanks to the collaboration of all its Departments, has been strengthened through the participation of its experts in forums, meetings, seminars, working groups or other projects associated with different international organizations, the provision of technical assistance and the organization of courses and seminars.

CELAD's international commitment in this regard is particularly evident through its collaboration and cooperation with the National Anti-Doping Organizations of Ibero-America. It is interesting to note that in 2021 the project for the creation of the Ibero-American Anti-Doping Network (Red Iberoamericana de Lucha Contra el Dopaje - RILD) was successfully completed and formalized on May 17, 2021, during the Constitutive Assembly with the signature of the representatives of the NADOs from 23 Ibero-American countries.

CELAD actively participates in the following expert committees of the Council of Europe related to the fight against doping in sport and the traffic of illegal medicines:

Monitoring Group of the Anti-Doping Convention (T-DO):

This is the group in charge of monitoring the implementation of the Anti-Doping Convention. It constitutes a unique network of governmental experts, anti-doping organizations, and sports federations that lead the work of monitoring the anti-doping policies of its 52 States Parties.

To this end, this group establishes standards and prepares specific recommendations for the States.

Spain annually submits the Anti-Doping Questionnaire (ADQ), which we answer as part of our commitment as signatories to the Convention, as well as to demonstrate how we apply it.



CELAD annually coordinates the collection of the necessary data to adequately respond to the questionnaire, for which it carries out the relevant consultations with all parties involved in one way or another in the implementation of the Convention.

With this and other objectives in mind, a National Anti-Doping Platform was created in 2021 that integrates all the actors involved in the fight against doping in sport, which we have discussed in more depth in section 3.1.1.

Within the T-DO there are several advisory groups associated with different areas of work, in which CELAD has been actively participating: the T-DO LI Advisory Group on Legal Issues, concerning Legal matters, the T-DO COMP Advisory Group on Compliance, concerning compliance with the Anti-Doping Convention, the T-DO SCI Advisory Group on Science, on science, and the T-DO ED Advisory Group on Education, concerning Education. The latter created a subgroup, the Ad Hoc Drafting group of Education Recommendations, in which CELAD participates, which was tasked with drafting Education Guidelines aimed at supporting the creation and implementation of the anti-doping education program, as described in the new International Education Standard of the World Anti-Doping Agency.

In the framework of international cooperation in the field of doping, in the meetings of this group and its advisory groups, Spain together with the other States has put all its readiness into collaborating with the World Anti-Doping Agency and international sports federations.

### Ad Hoc European Committee for the World Anti-Doping Agency (CAHAMA)

This is a committee of experts primarily responsible for developing and coordinating the positions of States Parties to the European Cultural Convention towards the World Anti-Doping Agency (WADA), supporting the work of European public authority representatives on the WADA Executive Committee and Foundation Board, WADA standing and ad hoc committees, as well as at public authority meetings at WADA, and providing information, comments, guidance and advice to the Committee of Ministers.

Spain actively participates in all Committee meetings and has an excellent relationship with the other participants.

 <u>Committee of experts on minimising public health risks posed by counterfeiting of medical</u> products and similar crimes (CD-P-PH/CMED)

The CMED focuses on the protection of public health through risk management and prevention against counterfeiting of medicinal products, trafficking and marketing of illegal



medicinal products, and other related crimes, as well as on improving cooperation between the different parties involved in the Member States and other stakeholders in Europe and beyond.

This group is mainly attended by representatives and experts from Drug Regulatory Authorities of the States Parties, although some representatives from Customs Authorities, Police Forces, Anti-Doping Organizations, Private Organizations related to medicines, Pharmaceutical Industry Associations, and World Health Organization also participate.

Spanish NADO belongs to this committee since 2013, actively participating in its meetings and working groups. For example. In 2020, within this committee, a working group was created in charge of drafting a recommendation for the governments of the member countries regarding the theft, loss, and diversion of medicines from legal distribution chains in which CELAD participates.

CELAD also belongs to the Network of Single Points of Contact (SPOCs), created within the CD-P-PH/CMED with experts from Drug Regulatory Authorities, Customs, Police, and Justice.

This Committee has also developed the Know-X database. The Know-X database was created to collect cases of falsified and illegal medicines and medical devices that are detected in Council of Europe member states. The tool supports officials by providing a basis for the exchange of information; it encourages cooperation between SPOCs and it also allows for exchanging analytical information on falsified medicines testing within the Official Medicines Control Laboratories (OMCL) Network.

The database contains details on cases of illegal and falsified medicinal products, medical devices, adulterated or contaminated nutritional products, technical information on the testing performed, the authorities involved, and what actions were taken. It also features a forum where users can ask questions or share information of interest, related to the problem of falsified and illegal medical products and related crimes.

### **Collaboration and information exchange at the international level with other Authorities**

The CELAD has mechanisms for collaboration, coordination, and cooperation at the international level. The agents with whom we have collaborated and exchanged information in recent years are the following:

- World Anti-Doping Agency (WADA)
- Anti-Doping Organisations of other countries (NADOs): e.g. USADA, UKAD.



- RILD
- Network of Medicines Authorities in Ibero-America (EAMI Network)
- International Federations: e.g. IAAF
- EUROPOL
- INTERPOL
- Law Enforcement Agencies of other countries: e.g. French Gendarmerie
- Medicines Regulatory Agencies of other countries: e.g. MHRA (UK)

The objectives of international collaboration and information exchange with theses Authorities are among others:

- To detect and investigate conducts that may lead to the commission of violations of the Antidoping Convention of the Council of Europe, the UNESCO International Convention against Doping in Sport and the World Anti-Doping Code.
- To detect doping behaviour by International Athletes who use different training and competition venues during the season, sometimes away from the direct involvement of their NADO.
- In cases of international athletes, who may be subject to the jurisdiction of different NADOs, international information sharing can eliminate duplication in the area of out-of-competition doping control planning, the construction of the Athlete's Biological Passport, and the discovery of violations resulting from missed test allocations due to the Athlete not being present for Sample collection at the location/whereabouts where the Athlete's whereabouts information was provided.
- Locate clandestine laboratories engaged in the production of doping products.
- Prevent the international marketing of instruments and raw materials used in the manufacture of doping substances.
- Prevent the import and shipment of products with a high risk of containing doping substances from other countries.
- Identify international trafficking and distribution networks, as well as athletes or endcustomers receiving products containing substances and for use in prohibited methods.

# Other collaboration with International Federations and NADOs by the Doping Control Department

Collaboration with International Sport Federations (IFs) and NADOs is usually carried out by the Doping Control Department and its Investigations and Intelligence Division. This collaboration is reflected in different areas of active interaction:



- Providing service in the sample collection request as a service provider. CELAD collaborates with IFs and NADOs in the sample collection of Spanish or foreign athletes who reside or train occasionally in our country. In this way, costs are reduced for these organisations, and these organisations also provide the same service to CELAD.
- The exchange of information through the ADAMS system relating to: test planning, locations, TUEs, and analytical results. This exchange of information and the signing of the relevant collaboration agreements has strengthened the Athlete Biological Passport (ABP) programme by accessing more than 800 passports.
- The exchange of intelligence information that facilitates targeted testing by coordinating CELAD's actions with IFs and NADOs, as well as providing information to support investigations of international non-analytical anti-doping violations.

### **Demonstration of clean performance through a negative Doping Control**

The service of CELAD as a Sampling Authority is regularly requested by NADOs, including International Federations so that in events where records are broken these can be validated, sometimes this activity generates certain complications when in the event there are no scheduled controls and therefore the control mission after the record must be organized within a maximum period of 24 hours.

### NØDopWeb and NØDopApp in Ibero-America

In 2019 CELAD launched in Spain the new tools <u>NØDopWeb</u> and NØDopApp, for consultation of substances and methods prohibited in sport for the prevention and fight against doping, to facilitate the search for medicines and doping substances in an easy and accessible way for both athletes and coaches, technicians, health and other athlete support personnel.

Both allow you to search by entering the name of the substance, the medicine, or the national identification code. Once the substance or medicine has been selected, both tools provide information on whether or not the substance or medicine, as well as the substance or substances it contains, are prohibited or not, as well as possible restrictions on its use.

The consultation also provides information on the classification of doping substances as reflected in the current List of substances and methods prohibited in sport (Prohibited List).

There is also a section on the health risks associated with the illegal consumption or use of substances and methods prohibited in sport, outside the authorised indications, to increase



sporting performance or muscle mass, and the additional risks associated with the consumption of illegal and counterfeit medicines, which are so common in doping.

These tools are intended not only as a platform for consultation but also as a tool to raise awareness of the inappropriate use of banned substances in sport and the medicines that contain them.

This work was carried out in collaboration between the Spanish Agency for Medicines and Medical Devices (AEMPS) and CELAD, and there is currently an automatic updating system that uses its database of both medicines registered in Spain and their active ingredients.

Since its creation NØDopWeb and NØDopApp have continued to offer the consultation service of substances and methods prohibited in sport, updating their content daily. Likewise, throughout the year, all queries and doubts received regarding medicines and other products consumed by athletes have been resolved.

In the NØDopWeb and NØDopApp development project, once the project was implemented in Spain, the possibility of integrating the Latin American countries that wish to do so was considered.

This collaboration began in 2019 as NØDopWeb and NØDopApp were the official consultation tools for the LIMA 2019 Pan American and Parapan American Games, which kicked off the second phase of the project, which is the collaboration with the rest of the National Anti-Doping Organisations (NADOs) and Medicines Regulatory Authorities (MRAs) of the Ibero-American countries, with whom work is beginning to integrate, to finally be able to consult the authorised and marketed medicines of all Ibero-American countries.

In 2020, the pandemic situation hampered the planned integration with various Ibero-American countries. Despite starting the process again in 2021, the process continues to be delayed, with the hope that it can be carried out in 2022-2023.

Additionally, during the year 2023, a series of important improvements are planned for NØDopWeb and NØDopApp, including the components of food and food supplements, a system for consulting the certification of the absence of doping substances in food and food supplements, information about medicines and food detected or withdrawn for being adulterated or contaminated with prohibited substances, a system for reporting to the competent authorities on medicines and food, as well as accessible tools for people with disabilities, etc.