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ARE SPANISH REGULATORS CONSTRAINING HUMAN PROCREATIVE DEMANDS?

¿ESTÁN LOS REGULADORES ESPAÑOLES RESTRINGIENDO LAS DEMANDAS DE TRATAMIENTOS PROCREATIVOS HUMANOS?

MONACO, Mario
Profesor Asociado, Universidad de Córdoba, Departamento de Derecho Público y Económico, Área de Derecho mercantil

Correspondence:
mmonaco@uco.es

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SUMMARY

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ABSTRACT

The Spanish regulatory framework related to assisted reproduction technologies (ART) is relatively permissive, and the country has become the leading one in that field in Europe, as well as a privileged destination for patients coming from other countries seeking heterologous treatments. An intensive exchange of tissue and cells is taking place worldwide, and it is desirable to maintain global standards. While broad legislation arises from European Union (EU) directives, in a way to maintain common standards that may reassure the public that human tissues and cells procured in other Member states carry the same guarantees as those in their own country, significant regulatory barriers to exercise procreative rights have been experienced recently in Spain through stricter interpretation by the actual public regulators, especially affecting biological sample distribution and its import or export. The issue is to establish a pattern of interaction among the subjects involved (politics, administrations, inspectors) to address the legal requirements and social needs guided by uniform regulation and clear engagement in practice.

RESUMEN

El marco regulatorio español en materia de tecnologías de reproducción asistida (TRA) es relativamente permisivo; el país se ha convertido en líder europeo en este campo, además de un destino privilegiado para pacientes del entorno que buscan tratamientos heterólogos. Actualmente, se observa un intenso intercambio de tejidos y células a nivel mundial, y es deseable mantener estándares globales. Si bien las Directivas de la Unión Europea (UE) establecen una legislación específica que busca mantener estándares comunes para garantizar a los ciudadanos que los tejidos y células humanos obtenidos en otros Estados miembros cuenten con las mismas garantías de su propio país, recientemente se han experimentado en España importantes barreras regulatorias para el ejercicio de los derechos reproductivos debido a una interpretación muy estricta por parte de los reguladores públicos, la cual afecta especialmente a la distribución de muestras biológicas y a su importación o exportación. La cuestión radica en establecer un modelo de interacción entre los actores involucrados (políticos, administraciones, inspectores) para abordar los requisitos legales y las necesidades sociales, guiados por una regulación uniforme y una clara observación de las reglas en la práctica.

KEYWORDS

Cryo-preservation, human reproductive sample, import and export, tissue establishments, transport.

PALABRAS CLAVE

Crioconservación, muestra reproductiva humana, importación y exportación, establecimientos de tejidos, transporte.

I. INTRODUCTION

Since the first conceived *in vitro* baby was born in 1978[1], it has been estimated that more than nine million births have been given worldwide as a result of assisted reproductive treatment (ART)[2], confirming its significant impact to help people obtain parenthood in the current society.

Thanks to the pioneering implementation of innovative and relatively permissive regulation for its time, Spain has become one of the leading countries in the field of ART and a privileged destination for citizens coming from surrounding areas. In a country with clear birth decline[3] (as well as the rest of the continent), the reproductive industry currently represents considerable revenue for its economy; according to research made in 2023, the global volume in the business reached 820 million euros (including private and public sector), an amount which has been growing unceasingly over the years[4].

The presence of an established culture of anonymous gamete donation for reproductive purposes had favored heterologous fertilization treatments in the Spanish clinics, the prohibition of which in other European countries (or at best, the recent regulations) has opened an insurmountable gap in favor of Spanish Tissue Establishments (TE) which hegemony continues to be significant due to its high competitiveness too[5].

However, it must be acknowledged that the particularly open legislation regarding ART techniques has not always been accompanied by the necessary public, ethical, and legal debate. Some authors have expressed the perception that in Spain, any new advancement or medical progress in this area has been accepted as scientific pro-

1 MATA-MIRANDA, Mónica Maribel, & VÁZQUEZ-ZAPIÉN, Gustavo Jesús, "La fecundación in vitro: Louise Brown, a cuatro décadas de su nacimiento", *Revista de sanidad militar*, vol. 72, núm. 5-6 (2018) 363-365. BRINSDEN, Peter R.; BRINSDEN, Peter R., "Thirty years of IVF: the legacy of Patrick Steptoe and Robert Edwards", *Human Fertility*, vol. 12, núm. 3 (2009), 137-143.

2 ADAMSON, G. David, CREIGHTON, Prudence, DE MOUZON, Jacques, ZEGERS-HOCHSCHILD, Fernando, DYER, Silke, & CHAMBERS, Georgina M., "How many infants have been born with the help of assisted reproductive technology?", *Fertility and Sterility*, vol. 124, núm. 1 (2025). According to the authors, from 9,829,668 to 13 million up through 2018.

3 According to the official Instituto Nacional de Estadística (INE), *Movimiento Natural de la Población / Indicadores Demográficos Básicos. Año 2023*, November 20, 2024, during the year 2023, 320,656 births were registered in Spain, which is a decrease of 2.6% compared to the previous year; births given by mothers born abroad accounted been 31.3% of the total amount. https://www.ine.es/dyngs/INEbase/es/operacion.htm?c=Estadistica_C&cid=1254736177003&menu=ultiDatos&idp=1254735573002 [accessed July 24, 2025].

4 According to the DBK INFORMA, *Los más de 300 centros de reproducción asistida ingresaron 630 millones en 2023*, (Sectorial Observatory, Cesce branch), the private centers specializing in the implementation of assisted reproduction processing generated a volume of aggregated business of above 630 million euros in 2023. Considering also the activity carried out in this area by public hospitals, it is estimated that the total value of assisted reproductive treatments carried out in Spain was around 820 million euros in 2023; *https://www.dbk.es/es/detalle-nota/centros-reproduccion-asistida-2024* (accessed July 24, 2025). SÁNCHEZ, Nacho, "El gran negocio de la reproducción asistida: luces y sombras de la industria de hacer realidad un sueño", El País, June 3, 2020, at 1. *https://elpais.com/elpais/2020/06/03/buenavida/1591208919_940726.html* [accessed July 24, 2025].

5 CHIALE, Stefania, "Festa per le gemelline al Niguarda: sono le prime nate da fecondazione eterologa con la Sanità regionale", *Corriere della Sera*, October 7, 2020, *https://milano.corriere.it/notizie/cronaca/20_ottobre_07/festa-le-gemelline-niguarda-sono-prime-nate-fecondazione-eterologa-la-sanita-regionale-64d28d1e-08c3-11eb-ab0e-c425b38361b4.shtml* [accessed July 24, 2025]. The newspaper reported on a bureaucratic process to obtain heterologous fertilization treatment within the Italian health system, which lasted more than five years, following appeals, rulings, counterclaims, and deliberations until the first births were achieved in a public hospital.

gress, making the country a preferred destination for cross-border reproductive care (CBRC)[6].

While this assertion may be acceptable regarding some types of reproductive treatments (*in vitro* fertilization, in particular), it clashes with the fact that gestational surrogacy, for example, has always remained imperatively prohibited in the country[7], in addition to further limits that have been added recently for surrogacy taken abroad[8]. The tangible impression is that the regulation set over the matter has always been conducted by legislators according to their prevailing ideology, without public debate and consultation.

In any case, this model of openness to new techniques and scientific advances generally enjoys a positive appreciation in Spanish civil society, considered an indicator of healthcare quality that generates significant economic benefits and employment opportunities.

II. THE CONGRUENCE OF CBRC IN SPAIN: AN OLD ISSUE WITH NOVEL POINT OF VIEWS

In a new context of global, intercultural and extraterritorial family in which diverse paradigms coexist, the legal discipline in the field of ART results often incomplete especially in terms of operational rules; the European Union (EU) made its efforts issuing many Directives on the matter (EUCTD)[9] and a more recent Regulation[10]; however, contemporary developments and circumstances face challenges where efficient responses are not often discernible.

These conditions favor (or trigger) various mechanisms, among which, for the matter, stands out the phenomenon of CBRC, which allows access to reproductive treatments that, for various reasons, are unavailable in one's own country. A model in which the 'conflicts of cultures' also come into play, which constitutes the predominant characteristic of Comparative Law and current Private International Law, as it has been authoritatively stated[11].

From some perspective, the CRBC has been defined as blameworthy since it leads to extreme or hazardous cases such as egg donation to obtain pregnancy in old women or sex selection, among the favorite trends often reported by the mass media[12]. From another point of view, it helps to find solutions for certain categories of patients who are not eligible for ART in their own coun-

6 PENNINGS, Guido, "Armonizzazione legale e turismo riproduttivo in Europa", *Giornale italiano di ostetricia e ginecologia*, vol. 27, núm. 7-8 (2005), 247-256. BORINI, Andrea, FLAMIGNI, Carlo, *Fecondazione e (s) terologa*, Rome, L'Asino d'oro, 2012.

7 Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida, Article 10.

8 See, Instrucción de 28 de abril de 2025, de la Dirección General de Seguridad Jurídica y Fe Pública, sobre actualización del régimen registral de la filiación de los nacimientos mediante gestación por sustitución, in which birth registration through foreign certification, nor judgments, issued by the authorities of the country where birth is given by surrogacy is now banned.

9 See MYINT, Peter, "Legal Framework for international operation of tissue banks", en PHILLIPS G. O. (ed.), Legal Basis of Global Tissue Banking, (2015), 13-30.

10 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, OJEU, July 7, 2024, L series.

11 JAYME, Erik, *Identité culturelle et intégration: le droit international privé postmoderne*, Martinus Nijhoff, Leiden 1995.

12 Lucio Cristina G., *El riesgo de ser madre a los 60*, El Mundo, September 16, 2016, https://www.elmundo.es/salud/2016/09/16/57dae6d5268e3ee72b8b4633.html [accessed July 24, 2025]. See FERRARETTI, Anna Pia, PENNINGS, Guido, GIANAROLI, Luca, NATALI, Francesca, MAGLI M., Cristina, "Cross-border reproductive care: a phenomenon expressing the controversial aspects of reproductive technologies", *Reproductive biomedicine online*, vol. 20, núm. 2 (2010), 261-266.

tries, and may offer better safety and quality of the treatments provided, balancing disparities among patients[13].

What is clear is that CRBC reduces the patients need to travel, activating a growing demand for the transfer of reproductive samples, also favored by other factors such as the awareness of belonging - in Europe - to a single market of services, the ease of access to widespread online information, and the aggressive marketing of those who have made large investments in clinics and biobanks capable of accommodating a large inflow of patients; moreover, all the reasons exposed are encouraged and dynamized in some countries where gametes donation is endemically unavailable.

Therefore, Spanish TEs are still maintaining the lead through the offer of treatments which involve female gametes (given the sufficiency of samples stored in biobanks), either attending patients in their premises or fertilizing the embryo in the laboratory with sperm coming from abroad, on purpose.

Despite this, a negative perception continues to soar around CRBC for the hostile consideration related to the movement of patients and human reproductive biological material, which would constitute an attempt to defraud the law and abuse the right in private international law, in addition to problems like the commodification of donations and the protection of donors' rights[14]. There are still authors who readily subjugate themselves to definitions such as 'reproductive tourism'[15], as if the solution to infertility problems evokes some kind of entertainment or amusement.

Nevertheless, as part of efforts to build a stronger European health Union, Regulation (EU) 2024/1938, concerning standards of quality and safety for substances of human origin intended for human application (SoHO), will replace shortly Directive 2004/23/EC: one of the milestones of the new Regulation focus to fulfill divergences between national rules, which have created obstacles to cross-border sharing of such substances to facilitating innovation for the benefit of public health[16] giving common rules to make CBRC more reliable under European citizens sight.

To build an actual European health Union, a legislation that ensures a high level of human health protection, in particular for SoHO donors, recipients and offspring from medically assisted reproduction is welcome and hopefully it shall help to overcome those hostile considerations and prejudices that still endure. Therefore, according to the new Regulation reproductive SoHO's exchange will improve patient access to therapies, and national barriers will be hopefully defeated in this matter to finally weaken the CRBC negative perception.

13 PENNINGS, Guido, DE WERT, Guido, SHENFIELD, Françoise, COHEN, Jean, TARLATZIS, Basil, DEVROEY, Paul, *ESHRE Task Force on Ethics and Law 15: Cross-border reproductive care*", *Human reproduction*, vol. *23*, núm.10 (2008), 2182-2184.

14 IGAREDA GONZÁLEZ, Noelia, "La donación anónima de gametos para para reproducción humana asistida en España: problemas y retos", *Revista de Bioética y Derecho*, núm. 38 (2016), 71-86, p. 79.

15 D'AMICO, Marilisa, "L'incostituzionalità del divieto assoluto della c.d. fecondazione eterologa", *Biolaw Journal*, vol. 2, núm. 22 (2014).

16 Regulation (EU) 2024/1938, cit., Whereas 5.

III. SPECIFIC CONSTRAINTS BY THE SPANISH REGULATOR: CARRIER'S STRONGER REQUIREMENTS AND LIMITATION TO DISTRIBUTION, IMPORT AND EXPORT OF REPRODUCTIVE SAMPLES

As the CBRC grew, the shipment of human reproductive samples in cryogenic containers has risen considerably in the last decade due to the encouraging results of cryo-preservation by vitrification of human gametes and embryos, which allows them to preserve all their characteristics during transportation[17]. In addition to 'intramural' transport, which involves shipping samples from/to laboratories of the same clinic (department or peripheral structure), shipping of reproductive samples is generally carried out at the 'external' level, to other remote TE by specialized couriers. Accordingly, specific limits and/or obligations imposed on the carriers have been observed lately in Spain.

1.- Carrier's requirements related to rail transportation

Distribution of human reproductive material enclosed in cryogenic containers called 'Dewars'[18] may be carried out by air, land (road or rail), or sea, depending on the distance and destination. It is clear that in some sensitive areas, such as airports[19], railway stations[20], and administrative buildings, security controls are arranged and mainly performed by X-ray machines, if luggage or cases are carried on; however, human samples exposed to ionizing radiation might produce harmful or lethal effects[21]. Therefore, at all airports, containers are usually inspected using alternative methods other than X-ray exposure in order to avoid such inconveniences; for this purpose, there are rules and regulations for the exemption of ionizing radiation sources, which establish alternative operating procedures, subject to prior notification and authorization by the airport management[22].

Nonetheless, for short-haul shipments, alternative means of transport are preferred. The reasons are: the lack of direct air connections and the reduced risk of sample survival due to the pressure changes they may experience on

17 RINEHART, Lisa A., "Storage, transport, and disposition of gametes and embryos: legal issues and practical considerations", *Fertility and Sterility*, vol.115, núm. 2 (2021), 274-281.

18 ROWLINSON, John Shipley, *Sir James Dewar, 1842–1923: a Ruthless Chemist*, London, Routledge, 2016.

19 ABEYRATNE, Ruwantissa, *Carriage of Dangerous Goods by Air*, Air Navigation Law, 175-194 (2012). MONACO, Mario, "Transport of Human Reproductive Samples and Regulatory Security Controls Systems in EU Airports", *Cuadernos Derecho Transnacional*, vol. 17, (2025), 1315-1322.

20 MONACO, Mario, "El transporte de las muestras reproductivas humanas y los controles de seguridad en las estaciones españolas de ferrocarriles: normativa, sugerencias y propuestas", *Revista de bioética y derecho*, núm. 62 (2024), 158-175.

21 GLOOR, Kayleen T., WINGET, Doug, SWANSON, William F., "Conservation science in a terrorist age: the impact of airport security screening on the viability and DNA integrity of frozen felid spermatozoa," *Journal of zoo and wildlife medicine*, vol. 37, núm. 3 (2006), 327-335. HENDRICKS, Katherine Elizabeth May, PENFOLD, Linda M., EVENSON, Donald P., KAPROTH, Michael T. & HANSEN Peter James, "Effects of airport screening X-irradiation on bovine sperm chromatin integrity and embryo development", T*heriogenology*, vol. 73, núm. 2 (2010), 267-272.

22 Commission Implementing Regulation (EU) 2015/1998 of 5 November 2015 laying down detailed measures for the implementation of the common basic standards on aviation security, Article 4. (Passengers and cabin baggage).

aircraft[23]. Likewise, Spanish TE preferably choose land-based means of transport, such as high-speed trains, due to their widespread network (the longest in Europe) and reliability.

In Spain, the law indicates that customers shall have the right to use rail transport services under the terms established in EU regulations and other applicable rules, such as contracts entered into with railway companies[24]. The State public administration and its dependent bodies should only ensure safety in rail transport at all times, while the public capital company called 'Administrador de Infraestructuras Ferroviarias' (ADIF) is responsible to apply safety regulations for the railway infrastructures and for the training and qualification of any person who perform tasks with possible impact on traffic protection, under current legislation[25].

In order to prevent the introduction of dangerous objects onto high-speed trains, the actual ADIF interpretation concerns that any carry-on baggage must be screened exclusively using X-ray machines in railway stations, with no exemptions, not even for Dewars containing human reproductive samples. Currently, no other alternatives are offered, even though it is known that such samples would be seriously harmed if subjected to these checks, with irreparable present and/or future consequences for next generations.

Therefore, given the responsibilities that ETs and transport operators would incur if cryopreserved samples were damaged by the consequences of controls carried out using X-ray machines, transport is currently not carried out by high-speed trains in Spanish territory.

That is indeed a limit for the actual and future exchange of reproductive SoHO, which aims to improve harmonization across EU Member States, according to Regulation (EU) 2024/1938 principles. While it is necessary to require security controls for high-speed trains in Spain, the actual restriction might easily be renewed: for instance, the stronger requirements related to air transportation may also be applied in Spanish railway's stations, replacing ionizing scanner for biomaterials with new model of inspections which are now widely accepted across airports in all the EU[26].

2.- Carrier's requirements in road transportation

In February 2012, the Spanish Constitutional Court ruled that legislating competence over the ART matter corresponds to the State and not to the regions (*Comunidades Autónomas*)[27]; this includes provisions relating to the transport of biological material.

23 CAMPOS LOZANO P., SÁNCHEZ CHIVA E., COELLO PERLES A., VALLEJO V., SERRANO DE LOS SANTOS J. & COBO A., "¿Existe relación entre el medio de transporte y los resultados clínicos en los ciclos de FIV realizados con ovocitos trasladados?", MEDRE, 24.2, 103-104 (2019), https://revista.asebir.com/assets/ASEBIR-REVISTA-CONGRESO-2019.pdf (accessed July 24, 2025). PARMEGIANI, Lodovico, MACCARINI, A. M., RASTELLINI A., BERNARDI Silvia, TROILO E., ARNONE A., LANZILOTTI S. & FILICORI, Marco, "Oocyte vitrification/storage/handling/transportation/warming, effect on survival and clinical results in donation programmes", Current Trends in Clinical Embriology, vol. 4, núm. 2 (2017), 34.

24 Ley 38/2015, de 29 de septiembre, del sector ferroviario, Article 62.1 (User Rights).

25 Id., Article 63.3 and 63.4.

26 MONACO, Mario, "Transport of Human Reproductive Samples and Regulatory Security Controls Systems in EU Airports", *cit*.

27 Tribunal Constitucional: STC 22/2012, February 16, 2012.

However, awaiting the Regulation (EU) 2024/1938 full application[28] and the consequences of its developments, the regions are still responsible for some major aspects: i.e., TE authorizations, collecting data related to TE activity, and, in particular, receiving contracts signed with couriers[29]. Nothing is said about the carrier's authorization for distribution; therefore, according to Article 36 of the same law, the regions just inspect the TE every two years and verify the compliance of the agreements with said specialized carriers, in case the distribution is commissioned to these third parties.

Accordingly, the inspection of local authorities has recently revealed non-compliance with some regulatory requirements that have often emerged in practice and other supposed ones that are difficult to sustain. Although it is observed that TEs generally complies with the rules and guidelines of the sector especially regarding cross-border transfers (i.e. the allocation to specialized carriers), a widespread use of conventional couriers occur for short-distance transportation, especially within the Iberian peninsula; in the absence of tight control by the authorities, TEs used to sign agreements with specialized carriers but continued, in some cases, to allocate the service to general couriers in a way to limit distribution costs: thus, human reproductive cells had often found themselves traveling 'in company' of goods and packages containing objects of all kinds and coming from everywhere.

In order to avoid inappropriate practices such as the one mentioned, it has recently been observed that, with a certain uniformity of intent, the Spanish regional authorities implemented specific sample transport requirements by reporting to the TEs certain obligations to be observed, which involve the operators carrying out the service. Regarding the actual guidelines and instructions, the regional authorities underline that agreements among third parties and TEs must include the following:

- Transport must be carried out by authorized carriers with a vehicle designated for this purpose that complies with special storage conditions and is able to guarantee the integrity of delivery at any time. The carrier's operators need to know the action plan required in the event of an incident and how to report it, following the established plans.

- It is also considered essential to ensure control of the hygienic conditions and periodic and/or extraordinary disinfection of the vehicle. The vehicle must have a kit of absorbent material, disinfectant, a waste container, and resistant gloves, among other protection measures, in order to avoid biological risks. Knowledge and compliance with the current legislation regarding the documentation transported must also be observed. The operator, preferably door-to-door, will be responsible for the custody and integrity of the samples and documentation to be delivered without having access to them.

Some other details are taken from the Agreement concerning the International Carriage of

28 Regulation (EU) 2024/1938, *cit.*, Article 87: it is already in force, but it shall apply from 7 August 2027, almost fully.
29 Real Decreto-ley 9/2014, de 4 de julio, por el que se establecen las normas de calidad y seguridad para la donación, la obtención, la evaluación, el procesamiento, la preservación, el almacenamiento y la distribución de células y tejidos humanos y se aprueban las normas de coordinación y funcionamiento para su uso en humanos, Article 24.7.

Dangerous Goods by Road (ADR) requirements; in detail, packaging must be resistant but lightweight (usually aluminum); likewise, the container must be equipped with its own protective 'suitcase' that allows it to withstand the rigors of transport and, if possible, must be designed to prevent improper positioning or tipping of the cryogenic container during transport. Dewars must be equipped with a programmable temperature monitoring system that allows the traceability of the same during the entire transit period (data loggers). These devices allow for the registration of the complete history of the measurements taken by the probe during the entire journey and can be easily downloaded, providing the exact temperature trend throughout the journey. In addition, the critical transport conditions must be well defined (e.g., temperature and time limits) to ensure that the required properties of the tissues or cells are maintained; all related serious adverse events must be identified and reported to the health authorities. All these requirements make it impossible for a conventional transportation company to be in charge and deal with human reproductive samples.

It has also been noted that compliance with the standards has sometimes resulted in further requirements and arrangements invoked by inspection bodies; on some occasions, TEs were required to sign an agreement with couriers that use containers which comply with International Air Transport Association (IATA) and International Safe Transit Association (ISTA) standards.

It might appear bizarre that Spanish regional authorities expect carriers to comply IATA air travel requirements also while road transportation is held as well as ISTA compliance: under the latter standards, containers have to be designed and produced according to tests which evaluate the packaging strength in a way to protect samples during transportation and distribution, minimizing damages; it is obvious that packaging for reproductive biological material has to stay safe during transportation but what appear unacceptable is that some public inspectors have suspended TEs authorizations for distribution because of carrier's ISTA non-compliance, which it seems to be an undue and excessive penalty under to the actual law and guidelines.

3.- Import and export of gametes

The import and export of reproductive samples is provided (and allowed) under *Real Decreto-ley* 9/2014, but is practically banned by the Spanish public administration in charge of issuing the permits. As for other cells and tissues, the law indicates that the procedure starts with a request to the National Transplant Organization (ONT), with the previous knowledge of the unit of the corresponding region. The Ministry of Health has to be informed of further formalities and issues a report. According to the actual rule about export, the TE has to demonstrate that providing gametes abroad does not affect the availability in the country and the existence of a medical reason justifying such transfer[30].

However, a recent official request to export oocytes out of the EU got the following answer from the Ministry of Health:

> "… after reviewing the documentation submitted by the requesting entity, the authorization was reported as 'unfavorable' based on Article 23.3b of *Real Decreto-ley*

30 Real Decreto-ley 9/2014, de 4 de julio, *cit.*, Article 23.3.

> 9/2014, which establishes the existence of a medical reason justifying such transfer as a necessary circumstance for authorizing the export of tissues and cells".

Actually, the TE demonstrated the existence of those 'medical reasons' issuing a patient's diagnostic of infertility; the requesting entity also indicate the need of oocytes donator with Spanish phenotype being those patients unable to recover them in the countries they live. Nonetheless, the authority added that Spanish law is to resolve infertility problems that occur among the Spanish population, or the foreign population that comes to resolve them in Spanish public or private clinics; it does not apply for said techniques to resolve infertility problems of the Spanish or foreign population that intends to resolve the same type of problem in clinics in other countries, whether or not they are linked through contractual relationships with the Spanish TE from which the request is made.

It is hard to agree to any aspect of the above unfavorable assessment; even if Article 23.3b of *Real Decreto-ley* 9/2014, establishes the need of a medical reason justifying the export of reproductive cells, the requesting entity actually produced a certificate of infertility which is the ground to establish ART treatment in Spain. Accordingly, the above-mentioned unfavorable decision is groundless: neither a diagnostic of infertility deficit of the receiving couple, nor the excuse of Spanish law that lacks the provision to resolve infertility problems in other countries may be received as the inexistence of a medical reason for gametes export, under any circumstances.

One, may say that medical reasons seems fairly straightforward in the field of ART but often they might not clearly be distinguished; for example, a remedy to a future infertility, genetic disease, cancer treatment or higher age that threat fertility, may be interpreted as a medical reason?[31] The affirmative answer is obviously easy to give to those cases; but what is also undoubtful is the infertility definition given by the World Health Organization (WHO) and other major organizations: a disease of the reproductive system *'characterized by the failure to establish a clinical pregnancy after 12 months of regular and unprotected sexual intercourse'*[32].

It is then clear that, according to the Ministry of Health, different regulations may apply: distribution in Spain and Europe versus export out of the EU, disregarding what regulated by the Cells and Tissues Directives and its transposition into Spanish law; the public administration should not interfere over permits at convenience and especially with different criteria. In this case, the doctrine of '*non venire contra factum proprium'*[33] should be invoked since it prevents public administrations from acting in contradiction with their own prior acts; based on good faith and consistency, it requires the administration to maintain predictable conduct and to avoid creating contradictory legal situations that harm those it serves, like in this case.

31 See PENNINGS, Guido, "Ethical aspects of social freezing", *Gynécologie obstétrique & fertilité*, vol. 41, núm. 9 (2013), 521-523.

32 VANDER BORGHT, Mélodie, WYNS Christine, "Fertility and infertility: Definition and epidemiology", *Clinical biochemistry*, vol. 62 (2018), 2-10.

33 See DE ENTERRÍA, Eduardo, "La doctrina de los actos propios y el sistema de la lesividad", *Revista de administración pública*, núm. 20 (1956), 69-80.

Furthermore, the application of Regulation (EU) 2024/1938 shall shortly establish the new frame of export activity as the one carried out to send SoHO from the Union to a third country[34]. Even if under some circumstances, Member States might adopt their own stricter rules, these measures should comply with EU law in general, and be proportionate and justified by the human health risks, including based on scientific knowledge. Besides, absolute transparency is required: if a country adopts such stricter rules, those have to be publicized as soon as possible, including on the internet and by the national authority to the EU SoHO Platform. Distribution import and export may be affected by national legislation about which the Regulation should not interfere, since it may deal with sensitive and ethical concerns for Member States. But if distribution applies, then import and export are applicable too under the same conditions. Therefore, SoHO export might be possibly banned by the Member State through its national legislation, not by the act of the public administration.

The above demonstrates that Spanish Ministry of Health had been clearly blind before the actual rule and new trends and measures to adopt; it seems that its particular field of competence had been overpassed. Thanks to the European legislator, export of reproductive SoHO shall be a matter that will help to ensure coherence in the EU, and hopefully out of the public administration area of influence.

4.- Compendia modifications despite having granted authorization related to embryo distribution

To provide a tool which may grant human reproductive tissues and cells traceability and hosted by the European Commission[35], the EU Tissue Establishment Compendium is a reference registry at the continental level as for the application of European Coding System for Tissues and Cells; it contains the list of all TEs authorized in the EU[36] and indicates their *status* by different letters: if authorized (A); on the other hand, (S) means that the authorization is Suspended, (R) Revoked or (C) stay for ceased activity.

The member state national registry is the basis on which the information is reflected in the European Compendium; accordingly, national authorities inform about the details to list, ensuring that accurate information is declared on the different types of activity as they appear in the European database.

Spain adopted a TE registry of activities through European Directive 2015/565/EU transposition and the system by which TE activity is recorded and declared is defined in *Real Decreto-ley* 9/2014: all the information is then collected and registered annually by the Spanish national authority (‘*Organización Nacional de Trasplantes*’, ONT), based on information submitted by the Spanish regional authorities.

34 Regulation (EU) 2024/1938, *cit.*, Article 3(30); that is to clearly distinguish it from ‘distribution’, which deals with providing SoHO within the EU according to Article 3(27).

35 European Commission EU Coding Platform, *EU Coding Platform Reference Compendia for the Application of a single European Coding System for Tissues and Cells*. The Compendium may be found at https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml [accessed July 24, 2025]. See CARAMIA, Valentina, GHIRARDINI, Angelo, DI CIACCIO, Paola, VESPASIANO, Francesca, MARERI, Maura & NANNI COSTA, Alessandro, “From the EU legislation to the application of the Single European Code: support to the implementation”, *Transfusion Medicine and Hemotherapy*, vol. 44, núm. 6 (2017), 391-394.

36 PRUß, Axel, “Coding of Tissue and Cell Products”, *Medicine and Hemotherapy,* vol. 44, núm. 6 (2017), 382.

However, in some cases, maintaining a harmonized registry of TE has proved to be quite difficult due to different models for granting authorizations in singular regions, especially when it comes to describing the type of activity[37]. Furthermore, lately some TEs report that their authorization (A) about embryos distribution 'vanished' from the Compendium after the latest update, even if they maintain the permission in their region: no letter appears in the box, and that emptiness has been felt as a preamble of future withdrawal of distribution authorization.

It is difficult to understand why the (A) letter disappears in the embryo distribution column only: either it is a system error which is unable to collect some data, or a human intended act directed to limit the embryo circulation. Neither circumstances would be acceptable and need urgently to be corrected.

IV. CONCLUSIONS

In the actual Spanish scenario descripted above, it seems that public administration is actually constraining human procreative demands through its own acts and decisions in a way to limit the exercise of some rights in the field. Limitation to distribution, import and export of reproductive samples, carrier's stronger requirements and rail transportation restrictions are only some of the examples that lead to this assumption.

The permissive Spanish legislation on the matter has showed through the year an excellent balance among political, ideological, and cultural diversities and orientations within a plural community, and constructed to respect the legal protection of differences, defending a cosmopolitan future. However, the functional integration between the law and the act of the public administration has to to be clearly improved; the increasing bureaucratic decision-making predominance is plainly observed in this context and that may lead to development of a direct self-regulation function, replacing the legislator role.

The application of Regulation (EU) 2024/1938 shall help to establish a new frame in which Member States will be more corseted and controlled. The adoption of guidelines or measures in a specific field are necessary and welcome but they need to enjoy the stakeholder and the relevant scientific community approval, not only the authoritativeness of the peripheral administration which cannot prevail over the law.

It is true that the excess of bureaucratization in Spain has indeed increased through the decentralized state structure, and some stricter policies are understandable since the matter of ART deals with human health, and the efforts of the legislator have to be taken into account. However, oscillating results due to harsher interpretation or alteration by the public regulator and inspectors will only serve to limit ART opportunities and finally lead to the Courts' scrutiny.

In a country with evident demographic decline, it is necessary to overcome the revealed difficulties to produce the necessary provisions capable of regulating the matter by identifying - during the processes of adoption of the rules - the legal discipline based on different fields (scientific, technical, ethical, etc.) also, avoiding the vision resulting by extreme positions that lack

37 Organización Nacional de Trasplantes, *Plan Estratégico Nacional de Tejidos 2022-2026*, April 5, 2022, at 80, https://www.ont.es/wp-content/uploads/2023/06/PLAN-ESTRATEGICO-NACIONAL-DE-TEJIDOS-2022-2026-Abril-2022.pdf [accessed July 24, 2025].

the necessary overall balance that -in general- leads to a poor balance. The issue is to establish a pattern of interaction between politics and administration that simultaneously addresses the requirements and social needs guided by political regulation.

To the extent that society understands (and accepts) that infertility is a disease rather than a discomfort or a whim and that having a child is a right rather than a wish, it will be possible to increase support - given the current state of science, law and bioethics - to ART techniques and, by extension, to citizens' reproductive projects.

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