



European Commission  
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**Subject: European donor register and common maximum limit on gamete donation**

Dear President,  
Dear Commissioner,

In recent days, European media have once again exposed a serious gap in the way we regulate cross-border gamete donation. According to a collaborative investigation by 14 public service broadcasters coordinated within the European Broadcasting Union (EBU), and reported among others by VRT, the BBC, El País and Euronews, a Danish sperm donor carrying a pathogenic TP53 mutation associated with Li-Fraumeni syndrome has allegedly fathered at least 197 children in 14 European countries via the European Sperm Bank. The donor's sperm is said to have been distributed over roughly 17 years to some 67 fertility clinics.

Earlier reporting on the same case, indicated that 67 children from 46 families in eight countries had already been tested, that 23 carry the TP53 variant and that at least 10 of them developed cancers such as leukaemia and non-Hodgkin lymphoma. Some of the children died as a consequence of this mutation. For other affected children carrying the TP53 variant this means, in practical terms, lifelong medical surveillance and cancer screening.

This case not only points towards deficits in the surveillance of (international) gamete donation, but also re-opens a wider discussion on the psychosocial impact of mass donation. According to research, donor-conceived people who discover, often through inexpensive DNA tests and social media, that they have very large numbers of half-siblings frequently report feelings of commodification, anxiety and loss of control over their own life story. They worry about the possibility of unknowingly entering into relationships with close genetic relatives, but they also describe the shock of finding out that they are one of dozens or even more than a hundred children linked to the same anonymous genetic parent spread across many countries. This risk has also been raised by ESHRE, during the last SCB meeting. From a regulatory point of view, the current scandal again highlights a structural weakness. While most Member States have national limits on the number of children or families that can be linked to a single donor, there is still no common limit, nor harmonised registry, at European or international level.

The European Sperm Bank now states on its website and in recent media statements that it applies a worldwide cap of 75 families for each donor, which by itself will easily lead to situations where children

have over 100 half siblings. According to Dutch reporting cited in European media, clinics were previously reassured that there are “rarely donors with more than 150 children”, which illustrates how high the tolerated numbers have been in practice. It is also important that, according to these sources, the 75-family cap has only been in place since 2023. This points to widespread mass donation as an accepted commercial practice. Even more concerning is the fact that other international commercial sperm banks still have no effective limit at all and practices that are sometimes questionable in terms of public health.

Belgium’s experience shows how difficult national rules can be enforced once donors and gametes start to move freely. The donor at the centre of this case fathered 53 children in Belgium alone, well beyond our statutory limit of six families per donor. Our Federal Agency for Medicines and Health Products (FAMHP) was informed by the Danish authorities only in 2023 and has since had to reconstruct retrospectively where this donor’s sperm was used and which families are affected. Fertility centres report that certain foreign sperm banks, even when they have contractually committed themselves to respect Belgian limits, do not in fact organise their practices in a way that ensures compliance. We have seen instances where sperm banks actively deliver material from the same donor to multiple clinics, almost certainly making it impossible to comply with Belgian quota. Others do not provide timely information that is essential for proper biovigilance when a serious hereditary risk is discovered.

In the absence of European rules, enforcement and traceability, this cross-border commercial market behaves – frankly – like a wild west. Decisions about how many children can be linked to a single donor are effectively made by private operators, responding to demand across borders, rather than by public authorities accountable to citizens and to the rights of the child. We see that the initial mission of offering people the possibility of a family has given way to a veritable fertility business, to the detriment of parents and children.

Our human-rights framework, by contrast, is quite clear. The United Nations Convention on the Rights of the Child recognises the child’s right to preserve their identity, including family relations, and to know and be cared for by their parents as far as possible. The Council of Europe has underlined that the right to know one’s origins has evolved into a distinct right closely linked to the right to identity and personal development under Article 8 ECHR. For the Union, this means that regulating the safety and quality of gametes under the SoHO framework is not enough. Children have a right to know where they come from, and their psychological as well as physical well-being must be at the centre of any European approach to gamete donation.

On the policy side, Belgium has been one of the staunch supporters of a European donor register and a European maximum limit on offspring per donor. We have argued for this consistently in the negotiations on the Substances of Human Origin (SoHO) framework and in Council discussions. We are not the only ones: during the EPSCO (Health) Council of 20 June 2025, Sweden, Belgian and Luxembourg, supported by , France, Hungary, the Netherlands and Spain, put an Any Other Business item on “International limits on the number of children per sperm or egg donor” on the agenda, calling for international limits on the number of children per donor and for a cross-border donor register. Furthermore, at the last European meeting of the SoHO Coordination Board, the European competent authorities all expressed their willingness and support for European harmonisation and a centralised registry.

On the eve of the implementation of the new SoHO Regulation, this scandal concerning donors and the use of their gametes calls into question its very purpose: the quality and safety of substances of human origin and the protection of donors, recipients, and children born from donations. In light of this, and in full awareness that similar situations are likely to emerge as more donor-conceived persons and families



gain access to genetic information, Belgium would like to renew its request that the Commission take concrete initiative at European level, in the interest of public health, quality and safety.

A key element should be the establishment of a European-level donor register that allows competent authorities to trace, in a pseudonymised but robust way, how often a donor has been used, in which Member State and in which clinic. Such a register should cover sperm, oocyte and embryo donors and should be designed so that national authorities can enforce family or offspring limits, organise cross-border biovigilance when serious risks are identified, and support donor-conceived persons who seek information about their origins. It is important that this register is not limited to future donations. Everything suggests that the TP53 case is only one visible cluster in a much wider pattern of mass donation. Clinics and cryobanks that operate on the EU market should therefore be required to submit historical data, as far as records allow, so that existing donor-conceived persons can know how many half siblings they have in Europe.

A second necessary step is the definition of a binding European maximum limit on the number of families or children per donor. National rules will remain relevant, but they are no longer sufficient once donors and gametes circulate freely. Commercial banks still defend practices which allow individual donors to reach offspring numbers well into three figures. A common European ceiling that is in line with the interests and mental health of donor-conceived persons is necessary.

Finally, the implementation of the SoHO Regulation is an opportunity to make traceability and biovigilance in gamete donation much more robust. The TP53 case shows that when a serious hereditary risk is detected the response has to be swift and coordinated across borders: suspending further use of the donor, informing all clinics and banks involved, and offering clear pathways and counselling for affected families. We count on the Commission to support Member States in ensuring that these rules are applied consistently and swiftly, so that this framework delivers real protection for donor-conceived children.

Belgium will continue to defend these positions in Council and in the implementation of SoHO, including through its leadership role in the SoHO Coordination Board. Only the Commission, however, can put forward a coherent European proposal for a donor register and a common maximum limit that matches the reality of a single market in gametes. In light of the urgency highlighted once again by this case, Belgium asks the Commission to take the necessary steps to strengthen the protection of the rights of donor-conceived children and to put in place the safeguards needed to prevent such scandals in the future.

With the highest regards,



**Frank VANDENBROUCKE**

Deputy Prime Minister and Minister of Social Affairs and Public Health, responsible for Poverty Reduction