

ESHRE position paper on international limits on the number of offspring per gamete donor

Stakeholder review report

The draft of the position paper was published and open for public review between 18 November 2025 and 4 January 2026. During this period, 375 comments from 45 reviewers were received. In this report, all comments are published, along with the responses of the ESHRE working group that drafted the paper.

Nr	Reviewer name	Topic	Page	Line	Comment	Response/action
General						
1	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)	ESHRE's role			<p>ESHRE is dedicated to establishing guidelines for best practices and legal protocols, serving as a vital resource for evidence-based reproductive health and treatments. It's aims are not politically driven, nor does it represent the interests of it's members.</p> <p>While most European countries set national limits on the number of offspring per donor, there is no universally accepted international limit. ESHRE does not determine national protocols or limits and we do not agree with the premise of this position paper as country governments and regulators should establish their own laws and limits.</p> <p>ESHRE should lead with recognised professional standards, skills, and established best practices in accordance with the appropriate guidelines of a profession.</p>	<p>Thank you. It is part of ESHRE's mission to provide input into policy and legislative decisions relevant to the field of medically assisted reproduction at the European level. See https://www.eshre.eu/Europe for more information on ESHRE's policy and advocacy activities.</p>
2	Donor Conception Network	General			<p>We would like to commend the authors on producing an excellent summary of the situation and position paper. We only have a small number of minor comments/thoughts.</p>	<p>Thank you.</p>

3	Human Fertilisation and Embryology Authority (HFEA)	General		<p>As a UK regulator, the HFEA does not take positions on EU policymaking, but recognises the significance of cross-border gamete use for UK patients, donors and donor-conceived people.</p> <p>The HFEA is broadly supportive of the recommendations outlined in the position paper.</p> <p>The HFEA can only regulate activity within UK licensed fertility clinics and has no legal remit over how donations are used outside the UK. However, we have long been concerned that while there is a family limit in places on donations within the UK, the increase in the use of imported sperm by UK patients, and in the export of UK donor sperm, means that many donor conceived people in the UK will have many donor related siblings outside of the UK</p> <p>The HFEA issues guidance to UK licensed clinics through our Code of Practice about the maximum number of families one donor can help create. In the UK, a donor's eggs, sperm or embryos may be used to help create up to ten families, (or a lower limit specified by the donor). The rationale for this limit is that consultation indicates that this is the level which donors and donor-conceived people feel comfortable with in terms of the numbers of potential donor-conceived children, half-siblings and families that might be created.</p> <p>The absence of any global or European limit on how many families can use the same donor, combined with the fact that family-limit rules vary widely between countries (and may not exist at all), means that large numbers of donor-conceived individuals are being created from the same donor. Donated sperm, eggs or embryos may be used both in the country where they were donated and in any countries to which they are exported, so patients may receive gametes from abroad while donors' gametes may simultaneously be used in multiple other countries. As a result, any national limit, such as the UK's 10-family limit, reflects</p>	Thank you for providing these insights into the UK's national situation.
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					only part of the overall picture, as a donor could help create many more families internationally even where national limits are not exceeded. In addition, family-limit rules usually apply only to donations made through licensed clinics. Donations made privately fall outside these systems and can further increase the total number of genetically related children across borders.	
4	London Sperm Bank	Overall position and framing			We strongly support ESHRE's overall direction: (i) prioritising the wellbeing and dignity of donor-conceived people, (ii) adopting family-based rather than child-based limits, and (iii) recognising that consanguinity is no longer the primary driver for offspring limits. We also agree that a harmonised framework is preferable to restricting cross-border exchange.	Thank you.
5	Mary Wingfield	Overall document			Overall, I think this is an excellent document. I have 2 suggestions/comments.	Thank you.
6	Melinda Ildiko Mitranovici	General			This is an important topic with a comprehensive approach	Thank you.
7	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies	Overall			We appreciate the research, dedication, and thoughtfulness taken to put this position together as it highlights many aspects and viewpoints relating to limiting family units.	Thank you.
8	CECOS (Centre d'Etude et de Conservation des Oeufs et du Sperme) Federation	The subject			<p>Firstly, we would like to thank ESHRE for its willingness to take a stance on the issue of limiting internationally the number of offspring from a single gamete donor. It is true that several countries within Europe have set their own limits, and there are significant variations between them.</p> <p>The international dimension of the issue has been overlooked until now, which has allowed several commercial banks to decide on their own rules, without ever losing sight of their main objective, which is to maintain a certain level of profitability. However, for any organization whose purpose is to distribute</p>	Thank you.

					gametes around the world, an international limit is necessary to respect recipients, donor-conceived people, and donors. The ESHRE's proposed recommendation is well-argued and clear, considering all those involved and all aspects of donation.	
9	Marilyn Crawshaw	General			I think you've done a very good of pulling this together so my comments are offered in that light. I was part of the working group some years ago that resulted in the publication you cite by Janssens et al (2015) so I know how hard it can sometimes be to find common ground. It would be good if there were to be a way of including the UK in any EU scheme.	Thank you.
10	Fertility Exeter	Consensus			In agreement with proposals.	Thank you.
11	Fertility Exeter	Appropriateness			Timely	Thank you.
12	Francoise Shenfield	General			Excellent and timely	Thank you.
13	Astrid Indekeu	general			A sincere thank you to the working group/ESHRE for picking up the concerns regarding the number of donor offspring per donor on a European/world level and to develop a position statement	Thank you.
14	Board of Health and Welfare (Sweden)	EU limits			We are strongly in favour of international limits	Thank you for sharing your position.
15	Dutch Society of Obstetrics and Gynecology (NVOG)	General			<p>We support the development of a European, or preferably global, guideline regulating the maximum number of offspring per gamete donor. With respect to the substantive concerns regarding the well-being of donor-conceived children, we fully endorse the concerns articulated in the position paper. We further believe that transparency and comprehensive counseling about the potential risks associated with current practices—for all stakeholders involved, including donors and intended parents—are essential to enabling informed decision-making that prioritizes the best interests of the donor child.</p> <p>Within the Dutch gynecological community, there is ongoing debate about the desirability of restricting cross-border gamete exchange. Some gynecologists</p>	Thank you for providing these insights into the Dutch national situation.

				<p>argue that such exchange should be discontinued altogether, while others maintain that it may continue under strict conditions. These conditions include guaranteed future access for donor-conceived individuals to donor identity information, as well as clear, transparent, and enforceable limits on the number of offspring per donor.</p> <p>Recent Dutch developments illustrate the challenges associated with enforcing such limits in practice. An amendment to the Dutch Act on Donor Data for Assisted Reproduction revealed that, despite the existence of national guidelines, an excessive number of children have been conceived per donor. This revelation attracted significant media attention and has reinforced the sense of urgency for stronger regulation in the Netherlands. While an international guideline would already be an important step forward in the short term, we emphasize that binding legislation is ultimately necessary to ensure effective and consistent enforcement.</p>	
16	Anonymous	General remark		<p>This is an ethics document that should convince people that a certain change is recommendable. However, it starts from the idea that limiting the use of the donor is good because some people say so and then goes on to elaborate on how to enforce this position. The arguments and underlying principles are largely lacking and make this document little more than a statement without foundation. These recommendations are formulated in a style that resembles administrative and legal rules. This is supposed to be an ethics document, not a legal outline of how to force people who disagree to behave in a certain way.</p>	<p>Thank you. This document does not form part of the Ethics & Law paper series. It is a policy paper, aiming to make concrete policy recommendations to the EU. See also other ESHRE policy position papers: https://www.eshre.eu/Europe/Position-statements</p>

17	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)	The impact of donated gametes		<p>Lack of national regulation can result in large numbers of children conceived from the same donor, through in person sperm donation, egg harvesting and exported embryos across borders. Whilst this position paper also addresses the complexity and acknowledges the impact of children born from donor conception regarding the “geographical spread of donations”, there is no critical exploration or discussion of prohibition and the ‘limits’ proposed are approached from the wrong direction.</p> <p>We would like to see tighter regulations, not a relaxation or liberalisation of restrictions on donor limits so to motivate or use as widely as possible, the sperm or eggs that have been ‘donated’. If an international agreement of a ‘limit’ to 50 families this could easily and predictably result in a ‘sibling pod’ of 100+ children.</p> <p>We would advocate for fewer than the UK legal limit of 10 families as if every family has two children 19 siblings is already a substantially large group of siblings to know and visit on a regular basis to establish clear and strong family links as an adult, possibly with your own children.</p> <ol style="list-style-type: none"> 1. Legal Requirement for Disclosure - it should be mandatory to inform donor-conceived children of their status by the time they reach adulthood. 2. Ban on Importing Donor Gametes - the importation of donor eggs, sperm, and embryos into the UK should be prohibited, limiting donation to British citizens and residents with settled status, facilitating potential contact with genetic parents. 3. Ban on Exporting Gametes and Embryos - the export of gametes and embryos from the UK for fertility treatments or surrogacy must be prohibited to prevent commercial surrogacy and illegal embryo selection abroad. 4. Criminal Offense for Travel -traveling abroad for implantation using anonymous gametes should be 	<p>Thank you. The introduction of any EU-wide limit is a tighter regulation, not a relaxation or liberalisation. Currently, there is no EU-level limit. Gametes are distributed to multiple countries who each only apply their national limits locally in their own country, leading to family numbers far above 50 across the EU. The position paper states "This international limit is not intended to replace national limits, but rather to complement them. Current national limits should still be upheld if they are lower."</p> <p>Policy recommendations at the UK national level are considered outside of the scope of this paper.</p>
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					<p>criminalized to uphold UK laws against sex selection and protect donor-conceived individuals.</p> <p>5. Criminal Records Checks - individuals who purchase or wish to import/export donor gametes and embryos must undergo criminal records checks, banning those with histories of violent or sexual crimes.</p> <p>6. Prosecution for Informal Matching - anonymous usage of donor gametes obtained through informal social media matching should be subject to criminal prosecution, with social media companies held accountable for related content.</p>	
18	Paths to Parenthub	General			<p>Firstly, here at <i>Paths to Parenthub</i> we welcome this important topic being discussed by ESHRE and feel changes to the current systems regarding the lack of international limits for donors are long overdue. For some context, <i>Paths to Parenthub</i> is a UK based organisation (but serves members internationally) established in 2020 by our founder Becky Kearns. Becky is a mum to three girls with her husband thanks to egg donation, and established <i>Paths to Parenthub</i> in response to a growing need for emotional and peer to peer support for those using donors to build their families. <i>Paths to Parenthub</i> is a growing platform that has over 400 active members, and over the past 5 years we have supported 1000s of individuals and couples via our membership platform, resources, podcast, and online/in person events. We support those considering donor conception as intended parents, those going through fertility treatment and those now parenting donor conceived children.</p>	Thank you for providing some background on your organisation.
19	Donor Conceived UK	General			<p>Donor Conceived UK (DCUK) fills a critical gap in the fertility landscape: We exist to ensure that those of us conceived through donation aren't left to navigate identity, emotional impact or complex family realities alone - often many decades after conception. As more people discover their origins via commercial DNA tests and seek answers, and the numbers of people using donor gametes to create their family increases, this</p>	Thank you for providing some background on your organisation.

					<p>need is only growing.</p> <p>The UK government, regulator and fertility industries focus has remained squarely on their duty of care in relation to the period surrounding treatments and donor recruitment and have largely avoided accepting any duty of care for the psycho-social fallout from the lifespan implications of creating life in this way.</p>	
20	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies	Responsible partners			<p>As long-standing leaders in the industry, we view ourselves as responsible partners in advancing ethical practices. We work closely with regulatory bodies and professional organizations to uphold the highest standards of safety, transparency, and integrity. Our commitment extends to protecting donors, recipients, and donor-conceived individuals.</p>	Thank you for providing some background on your organisation.
21	Cryos International Sperm & Egg bank	Ensuring fair access to donor sperm			<p>At Cryos Sperm & Egg bank we are aware of the strong voices advocating for tighter limits on the number of donor siblings, and we fully acknowledge the psychological perspectives and emotions underlying the desire to reduce the number of donor-conceived children per donor. However, as a sperm bank with direct insight into the real, and growing, demand for donor gametes, we believe that regulations cannot be guided by psychological considerations alone. They must also account for the very real consequences for individuals and families who rely on donor gametes to conceive.</p> <p>Restricting access through stricter limitations will inevitably affect supply and demand, leading to higher costs and longer waiting times. This comes at a human cost: tighter restrictions risk excluding lower-income families and creating socio-economic disparities in who has access to donor treatment. Prospective parents should not bear this burden. Any set of rules must carefully balance the needs of current and future recipients with the views of donors, who, to our knowledge, are generally not in favour of reducing the number of donor-conceived children but are instead motivated by altruistic desires to help more families</p>	Thank you for sharing your position. The feedback on the proposed approach was discussed extensively within the working group. Considerations on the impact on access to treatments were already included in the initial draft of the position paper, and the working group still considers that they do not generally outweigh the arguments for introducing an international limit, as long as this limit is implemented gradually and alongside mitigation measures. Therefore, the overall approach proposed in the position paper was not changed.

					<p>have a child.</p> <p>Providing information and advice to both donors and parents is the right way to deal with this issue, rather than attempting to control the international quota through regulation, which will only reduce supply and push even more people into the unregulated market. We attach great importance to making the limits of 50 and 15 optional but refrain from setting limits in general and trust in reproductive autonomy by allowing prospective parents to choose for themselves, but with full information, counselling and consent. For the vast majority of patients, choosing a gamete donor is not a medical procedure – just like normal reproduction, it is more like dating. Only in cases where the recipient is ill, which is very rare, e.g. not lesbians and singles, who account for >80% of demand it is to be considered part of the medical procedure.</p> <p>To contribute to evidence-based regulation, we are currently conducting a study among Cryos donors and customers on attitudes toward donor limits. The results are expected in early 2026, and we look forward to sharing our findings.</p>	
22	ASEBIR (Spanish Society of Reproductive Biology)	General			<p>On behalf of the Board of ASEBIR, we would like to express our strong support for ESHRE’s position paper on international limits on the number of offspring per gamete donor.</p>	Thank you.
23	Association of Reproductive and Clinical Scientists (UK)	UK view			<p>The Human Fertilisation and Embryology Authority (HFEA) in the UK set a 10 family limit for donation within the UK. However many couples (mis)-understand this to mean that the gametes can only be used to make 10 families internationally. From the UK perspective it therefore makes good sense to introduce an international limit for clarity and consistency.</p> <p>As ARCS we have previously supported the ESHRE information giving for donation which discussed the setting of such a limit. See ARCS Statement here: https://www.arcscientists.org/wp-</p>	Thank you.

					content/uploads/2023/10/Best-practice-in-information-provision-in-reproductive-donation..pdf	
24	Association of Reproductive and Clinical Scientists (UK)	Balancing needs for gametes vs offspring			There is a clear need for donor gametes, and we should not stigmatise those who need them for treatment unnecessarily through ‘fearmongering’ about large potential numbers of families; but clearly we should also be very mindful of the need to protect donor offspring. This proposal tries to strike that balance and should be supported and commended for that.	Thank you.
25	The Danish Business Association for Egg and Sperm Donation (BFSD)	General introduction			The Danish Business Association for Egg and Sperm Donation (BFSD) welcomes the ESHRE position paper on international limits on the number of offspring per gamete donor. The paper provides a thorough and well-researched foundation for discussion and raises many important considerations relevant to donors, recipients, and donor-conceived people. While BFSD does not agree with all conclusions or proposed measures, we recognise the value of the paper in advancing a necessary and timely debate. We support the introduction of an EU-wide family limit for gamete donors, provided it is implemented as part of a coherent and workable framework that reflects real-world practice and cross-border realities.	Thank you.
26	The Danish Business Association for Egg and Sperm Donation (BFSD)	Closing position			BFSD supports the introduction of an EU-wide family limit for gamete donors. However, protection is not achieved through restriction in isolation. Effective regulation requires a responsible and effective framework that works in practice — for donors, for patients, and for the people born as a result. Limits must be combined with: <ul style="list-style-type: none"> • A central EU registry and standards • Additional initiatives to support donor recruitment, aligned with the new regulatory framework • Standardised donor and gamete requirements and tightly enforced vigilance oversight • Clear conceptual distinctions about the role of donors • Ongoing evaluation based on data and lived 	Thank you for sharing your position. Most of the points listed are addressed in the paper. However, the working group considers details on donor and gamete requirements and vigilance oversight outside of the scope of the paper.

				<p>experience</p> <p>Only through such a balanced approach can Europe create a safer, more transparent, and more equitable fertility sector.</p>	
27	Hana Konečná	The fundamental difference between the recommendations of national organizations and ESHRE		<p>I understand the main objective of ESHRE to be that it is a professional organization that sets professional practice and lege artis procedures (serves as a primary source for evidence-based infertility care). It does not therefore represent the interests of applicants (that is the role of Fertility Europe), nor is it a political force whose operating principle is "the art of the possible." If the professional ESHRE recommendations differ fundamentally – many times over – from the recommendations of professional societies in individual countries (Appendix 1), something is wrong.</p>	<p>Appendix 1 does not present the recommendations of national professional societies for an EU-wide limit. It presents current limits to the number of offspring per gamete donors in different national legislations. These limits currently only apply locally and there is no EU-wide or other international limit. As stated in line 188 of the stakeholder review version, the proposed EU-wide limit "is not intended to replace national limits, but rather to complement them. Current national limits should still be upheld if they are lower."</p>
28	Annemieke Hoek	General comment		<p>We welcome the initiative of the ESHRE to set limits on the number of offspring per gamete donor. It is of utmost importance that the ESHRE considers the wellbeing of donor-conceived people to have the highest priority determining the limits on the number of offspring/ families. This ethical perspective should be the pivot of the position paper. From this ethical perspective, we have several major comments regarding the number of families per offspring and the duration of the distribution of the gametes (see below). We agree that the EU should set a legal basis for Eu-wide donor registry, including gamete imports from non-Eu countries. We agree that “pregnancy slots” should be set in place for clinics and gamete banks, in order not to exceed the number of families coupled to a donor. Furthermore, we urge the ESHRE to advocate European regulation with respect to inspection, audit for gamete donor banks and clinics using those banks.</p>	<p>Thank you for sharing your position.</p>

29	Stichting Donorkind	General comment		<p>We welcome the initiative of the ESHRE to set limits on the number of offspring per gamete donor. It is of utmost importance that the ESHRE considers the wellbeing of donor-conceived people to have the highest priority determining the limits on the number of offspring/ families. This ethical perspective should be the pivot of the position paper.</p> <p>From this ethical perspective, we have several major comments regarding the number of families per offspring and the duration of the distribution of the gametes.</p> <p>We agree that the EU should set a legal basis for Eu-wide donor registry, including gamete imports from non-Eu countries.</p> <p>We agree that “pregnancy slots” should be set in place for clinics and gamete banks, in order not to exceed the number of families coupled to a donor.</p> <p>Furthermore, we urge the ESHRE to advocate European regulation with respect to inspection, audit for gamete donor banks and clinics using those banks.</p> <p>In our perspective donorconception and all procedures using a donated gamete should fully respect the international treaty on the rights of the child. To do this medical organizations and professionals should only do their medical part. Donor and (all) prospect parents should be in full contact and have arrangements regarding respecting the rights of their children before any medical procedure is done. There is no right for parents or donors on isolating a child from their biological family. And there is no medical need to do this. Which means medical organizations and professionals overstep their professional boundaries by keeping donors and prospect parents separated and even making profits on selling information (all information is personal information of the donor conceived individuals).</p>	<p>Thank you for sharing your position. We consider the question whether donor-conceived people should be able to access the donor's identity outside of the scope of the paper, which is confined to limits to the number of offspring per gamete donor.</p>
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30	JUAN JOSÉ GUILLÉN	Anonymity vs. Openness)		<p>We observe a subtle bias in the document favoring the "identity-release" model predominant in Northern European countries, framing it as the ethically superior standard. We urge ESHRE to maintain a position of neutrality and respect towards the diverse socio-cultural realities of Europe.</p> <p>Practical evidence supports this need for plurality: Implementation varies significantly even among non-anonymous systems. For instance, the Portuguese model maintains a balance by making access to information effectively dependent on parental disclosure, respecting the private family sphere. In contrast, experiences in countries like the UK, where the state guarantees access independent of parental preference, have demonstrated that strict non-anonymity can lead to a significant decrease in donor numbers, threatening treatment availability.</p> <p>In Southern European societies, the anonymous or mixed model is deeply rooted and accepted as a protective measure for family privacy. ESHRE should defend ethical pluralism, recognizing that imposing a "one-size-fits-all" approach regarding nonanonymity alienates a significant portion of the European community, ignores the risks of donor shortages observed in other jurisdictions, and disregards the autonomy of families in these regions.</p>	<p>Thank you for sharing your position. We consider the question whether donor-conceived people should be able to access the donor's identity outside of the scope of the paper. Considerations on contact between donor-conceived people and donors are included in light of the fact that such access is granted in several legislations and taking into account reported cases of donor-conceived people identifying their donor through other means, despite the donor being promised full anonymity at the time of donation.</p>
31	Lisa Ransome	General Feedback to the Document		<p>While I am writing from the perspective of an Australian Psychologist, and not working within the EU. The impact of donor banks, is wide reaching, and does have impacts on Australian recipient families.</p> <p>Having worked with individuals and couples who have been the recipients of international donor gametes, whether from the EU or the USA, they often raise concerns regarding the number of donor siblings their child/ren may potentially have in the world, even with Australian limits varying between 5 and 10 families (dependent on state). While many Australian states have technical "worldwide" limits, this does not appear</p>	<p>Thank you for providing these insights into the Australian national situation.</p>

				<p>to be honored or respected by many clinics (see: https://www.abc.net.au/news/2025-09-20/monash-ivf-suspend-donor-treatmentnsw-family-limit/105794278 and https://www.abc.net.au/news/2025-10-02/fertility-treatments-to-proceed-after-nsw-health-exemption/105845260) and there is no legal ramification for these breaches.</p> <p>Increased complexity also arises when families are accessing “double-donation” increasing the number of donor-siblings this child would be connected to. By setting limits to what can be exported from the EU to countries outside in addition to, or inclusive of an EU limit, while this cannot be policed and legislated on an international basis, it still provides greater oversight and legislative powers than we currently have in the fertility industry.</p> <p>It is also noted harmonization of Australian laws around donor limits, and an Australia-wide donor register (rather than state based) would be advantageous, however it is acknowledged this is far beyond the remit of the EU legislature. However, if an EU precedent is set, then this may lead to greater harmonization of laws in other countries, including Australia, which can only be beneficial for donors, recipient families and most importantly donor conceived people.</p>	
32	Menno Hofman	Donor age		<p>The age of majority in the EU is 18, yet in some clinics a higher age is required for sperm donors. This is not in the interest of donor conceived, who will have less time for meeting the donor if the donor is older. It may help recruit more donors to lower this limit. When older, relationship/parenthood may make it harder to donate due to practical reasons. Obviously, the donor assessment should include making sure that the donor knows the lifelong responsibilities that come with becoming a donor.</p>	<p>Thank you for sharing these considerations. We consider age limits of gamete donors outside of the scope of this position paper, which is confined to limits to the number of offspring per gamete donor.</p>

33	Keerti Singh	Genetic Aspects and Medical aspects			<p>There is no information included regarding the age limit of the donors. This is important in terms of lower fertility outcomes, increased miscarriages and genetic mutations. In terms of social aspects generational gaps and family dynamics.</p> <p>Similarly, very young donors may produce gametes for many years, chances of producing high number of offsprings are there unless limits are enforced.</p> <p>- The above information can be included under the sub heading of social and ethical aspects</p>	<p>Thank you for sharing these considerations. We consider age limits of gamete donors outside of the scope of this position paper, which is confined to limits to the number of offspring per gamete donor.</p>
34	Solomütter Deutschland e.V.	Input from the German association for Single mothers by choice			<p>In addition, we advocate for the establishment of an international, voluntary donor-sibling registry that enables secure, privacy-protected access to information about donor siblings. Such a registry would support donorconceived people and families in making contact in a structured and safe way, and would reduce the need to rely on informal and unregulated searches through social media platforms such as Facebook.</p>	<p>Thank you for sharing this suggestion. We consider voluntary registries set up for other purposes than the monitoring of adherence to donor offspring limits outside the scope of this paper.</p>
35	ASEBIR (Spanish Society of Reproductive Biology)	Donor health			<p>We suggest considering as an indirect factor the health of donors, especially females, as a high limit of family units will imply that you can stimulate many cycles, though there is no evidence yet.</p>	<p>Thank you for sharing this consideration. The proposed family limits in this position paper are to be understood as a maximum that should not be exceeded, not as a number that should be aspired to. The working group agrees that protecting the health of oocyte donors is of utmost importance. However, we consider that the potential harms of multiple stimulation cycles should rather be prevented by directly limiting the number of stimulation cycles that a donor may undergo, since several stimulation cycles in one donor can result in the same number of families as a single cycle in another donor. This topic is outside of the scope of the present paper, which is confined to limits to the number of offspring per gamete donor.</p>

36	Juan Manuel Moreno-Moya	OPUs			<p>I think that a limit amount of egg retrievals per donor it would be also adviceable to prevent too many interventions in a woman that can compromise her health.</p> <p>Are there any minimum requirements of AMH and AFC that can be also standardized to use as recommendation for inclusion in donor programs or not?</p>	<p>Thank you for sharing this consideration. The proposed family limits in this position paper are to be understood as a maximum that should not be exceeded, not as a number that should be aspired to. The working group agrees that protecting the health of oocyte donors is of utmost importance. However, we consider that the potential harms of multiple stimulation cycles should rather be prevented by directly limiting the number of stimulation cycles that a donor may undergo, since several stimulation cycles in one donor can result in the same number of families as a single cycle in another donor. This topic, as well as AMH and AFC requirements for donors, is outside of the scope of the present paper, which is confined to limits to the number of offspring per gamete donor.</p>
37	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)	Sperm v Egg			<p>We understand that this position paper was motivated by Nordic Countries calling for international limits for both sperm and egg donations, however we suspect that the focus is largely on sperm donors due to the nature and practice of sperm donation, with the method of collection being non-invasive and the ease of travel for the purposes of donation. Women who donate their eggs have a much more involved procedure which is lengthy, invasive and risky. This inequality is notable that each sperm donor can provide significantly more genetic material over their lifetime than each egg donor.</p> <p>The biological and procedural differences strongly advantage men in donating more frequently and with less physical strain, leading to a greater number of total sperm donations compared to egg donations from women.</p>	<p>Thank you for sharing these considerations. The working group agrees that there are important differences between oocyte and sperm donation. However, considerations on the implications of offspring numbers for donors and donor-conceived people are similar for both types of donation. While large numbers of offspring are less likely for oocyte donors than for sperm donors, it is still possible that offspring numbers from some oocyte donors reach levels for which the limits proposed in this paper are relevant.</p>

					<p>As single issue campaigns that focus on law reform on surrogacy, we see a significant overlap and risk associated with egg donation and campaign collectively with others to raise awareness of the impact on women in terms of medical risks and social perceptions as well as for children.</p> <p>We feel it is important to view egg and sperm donation as entirely different areas of medicine, beginning with the different procedures for gamete harvesting dependant on your biological sex to the health screening that are dependent on DNA, to the relationships and difficulties donor conceived people face when looking for their genetic mother or genetic father.</p>	
38	The Danish Business Association for Egg and Sperm Donation (BFSD)	Quality of care and monitoring			<p>Introducing an EU limit requires prior harmonisation of donor standards and oversight across Europe. Today, donor programmes vary significantly between national donor banks, international donor banks, and clinics with in-house recruitment, leaving patients unable to assess differences in quality and associated risks for themselves and donor-conceived children. Common European standards are needed for donor recruitment, screening, testing, documentation, and follow-up across all providers operating on the EU market.</p> <p>The handling of Adverse Reactions (ARs) illustrates the problem: some donor banks conduct systematic monitoring and report extensively via the Rapid Alert and Traceability System, while others report virtually no ARs. These discrepancies reflect differences in standards and oversight—not donor quality—and point to serious weaknesses that must be addressed. The SoHO Regulation aims to establish parts of these standards. However, EU donor limits cannot be implemented meaningfully without clearer alignment on donor quality and programme governance, and without effective EU-level monitoring and enforcement. In the absence of this, there is a real risk of a race to</p>	<p>Thank you for sharing these considerations. We consider standards for donor recruitment, screening, testing, documentation, and follow-up outside of the scope of this paper, which is confined to limits to the number of offspring per gamete donor.</p>

					the lowest common denominator, undermining patient safety and trust	
39	Hana Konečná	Oviedo Convention			In the Explanatory Report, Oviedo Convention states (point 119) that the use of part of one human body to treat another person is justifiable when "there exists no alternative therapeutic method of comparable effectiveness... if there is no other solution that would produce similar results." I find it completely lacking in expert discussion as to whether adoption, foster care, or childlessness are truly inadequate alternatives.	Thank you for sharing this consideration. We consider the question whether gamete donation as such is an acceptable practice outside of the scope of this paper, which is confined to limits to the number of offspring per gamete donor.
40	Annemieke Hoek	Legal aspects; And psychosocial aspects European human rights and international children's rights "The right of identity"			We think that the ESHRE should add and elaborate in the position paper "the right of identity" as depicted in European Human Rights and International Children's Rights law. Those laws include "the right of identity" under Articles 8 of the European Human Rights and art. 8 of International convention on the Right of the Child. "The right of identity" includes, among other things, the right to know from whom you descent and the right to know to whom you are genetically related. This means not only knowing these genetic ties, but also having the actual opportunity to get to know each other, your donor, the other donor conceived children of the donor, including those who belong to your genetic kinship. From this perspective, having a very large genetic kinship network is undesirable, and possibly harmful for the mental dignity of the individuals. There are various aspects to take into account: the genetic ties; from whom you descent this does not change over time (your donor), but also the fluidity of your identity whenever there is an ever growing network of halfsiblings. Within a family you would know your brothers and sisters from birth onwards. In a donor conceived network your half siblings "emerge" in large numbers and over a large number of years, which shapes your identity over time(e.g. being one of 10, as time goes by one of 20, and later one of 50 or even one of 100 or more) this changes the perspective of the own identity over time and is possibly harmful for the	Thank you for sharing your position. We consider the question whether donor-conceived people should be able to access the donor's identity outside of the scope of the paper, which is confined to limits to the number of offspring per gamete donor.

					<p>mental dignity of the individual. Recent publication in Dutch: of Nederlands juristen blad; 10-10-2025: afl. 31 pg 2599-2606. Bregje Dijksterhuis et al. (I will sent the manuscript in Dutch so the ESHRE can translate) Line 256-259; “SOHO entities shall mitigate any other avoidable risk to the health, including where related to the protection of dignity, in accordance with national law, of SOHO recipients or of offspring from medical assisted reproduction (article 58 SOHO Regulation)”; underscores the importance of mental dignity also for donor offspring.</p>	
41	Stichting Donorkind	<p>Legal aspects; And psychosocial aspects</p> <p>European human rights and international children’s rights “The right of identity”</p>			<p>We think that the ESHRE should add and elaborate in the position paper “the right of identity” as depicted in European Human Rights and International Children’s Rights law. Those laws include “the right of identity” under Articles 8 of the European Human Rights and art. 8 of International convention on the Right of the Child. “The right of identity” includes, among other things, the right to know from whom you descent and the right to know to whom you are genetically related. This means not only knowing these genetic ties, but also having the actual opportunity to get to know each other, your donor, the other donor conceived children of the donor, including those who belong to your genetic kinship. From this perspective, having a very large genetic kinship network is undesirable, and possibly harmful for the mental dignity of the individuals. There are various aspects to take into account: the genetic ties; from whom you descent this does not change over time (your donor), but also the fluidity of your identity whenever there is an ever growing network of halfsiblings. Within a family you would know your brothers and sisters from birth onwards. In a donor conceived network your half siblings “emerge” in large numbers and over a large number of years, which shapes your identity over time(e.g. being one of 10, as time goes by one of 20, and later one of 50 or even one of 100 or more) this changes the perspective of the</p>	<p>Thank you for sharing your position. We consider the question whether donor-conceived people should be able to access the donor's identity outside of the scope of the paper, which is confined to limits to the number of offspring per gamete donor.</p>

					<p>own identity over time and is possibly harmful for the mental dignity of the individual. Recent publication in Dutch: of Nederlands juristen blad; 10-10-2025: afl. 31 pg 2599-2606. Bregje Dijksterhuis et al. (I will sent the manuscript in Dutch so the ESHRE can translate)</p> <p>Line 256-259; “SOHO entities shall mitigate any other avoidable risk to the health, including where related to the protection of dignity, in accordance with national law, of SOHO recipients or of offspring from medical assisted reproduction (article 58 SOHO Regulation)”;</p> <p>underscores the importance of mental dignity also for donor offspring.</p>	
42	Astrid Indekeu	Law/yers			<p>ESHRE has a SIG ‘Ethics & Law’. There seems to be less presence/visibility of ‘the law -side’/ lawyers specialized in ART in ESHRE. As the world is getting more and more complex, with lots of legal questions (such as this question), it might be valuable for ESHRE to engage more lawyers</p>	<p>Thank you for this comment. As it is not directly related to this specific position paper, it will not be addressed further in this context.</p>
43	Michael Scholtes		?	Not adressed	<p>Where are the lawyers? Inheritance? If a regulation EU-wide is proposed, the legal position of donor offspring will be a matter of debate. In Germany there is still uncertainty about how courts of justice see donor offspring, in in the least in single mothers and homosexual couples. It is mandatory to offer germ cell donors assurances. Official, legally registered donors should be exempt from claims from their donor conceived offspring.</p>	<p>Thank you for this comment. We consider the legal parental status of donors to be outside of the scope of this paper, which is confined to limits to the number of offspring per gamete donor.</p>
44	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)				<p>General note on the presentation of this review document - this document is not fully accessible due to the logo watermark and may not meet criteria for WCAG 2.1 and 2.2 and the EAA.</p>	<p>Thank you for this comment. We will review within ESHRE whether the form to submit stakeholder comments can be adapted.</p>
Background						

45	Viville Stéphane		1	5	“Many people” is too vague	Thank you. Given that this is an introductory sentence and there is no single statistic available on the total number of people making use of gamete donation, it was decided not to go into detail on the numbers here. Instead the wording was changed to "A significant number of people" and a reference to the latest EIM publication was added.
46	Donor Conceived UK		1	5-6	RE Scope: Explanation required as to why this recommendation doesn't cover embryos? (embryos are not the same as gametes.)	Thank you. The scope was clarified in the paper. Embryos were not included because offspring numbers in embryo donation are by definition low, given that embryos are not created specifically for donation but only donated in case the original intended parents decide to offer them for donation.
47	Viville Stéphane		1	7	“relationship status” should be precised in brakets	This has been adapted in the paper.
48	Donor Conceived UK		1	7-9	Although countries may have national limits, they don't always have a nationally organized system for keeping to those limits. The potential results of this have been shown starkly in Belgium in relation to the recent case involving the ESB sperm donor as you acknowledge later on. We know you deal with the need for this from line 130 on but we suggest you make clear at this point that not all countries with limits have a national system in place.	This has been adapted in the paper.
49	Marilyn Crawshaw		1	7-9	Although countries may have national limits, they don't always have a nationally organized system for keeping to those limits. The potential results of this have been shown starkly in Belgium in relation to the recent case involving the ESB sperm donor as you acknowledge later on. I know you deal with the need for this from line 130 on but I suggest you make clear at this point that not all countries with limits have a national system in place. Would only need a few words	This has been adapted in the paper.

50	Cryos International Sperm & Egg bank		1	10	It is not only gametes that are exported, but also patients seeking treatment in countries other than their country of residence, CBRC, and therefore both exporting and importing gametes to/from countries other than their country of residence.	This has been adapted in the paper.
51	Astrid Indekeu		1	10	Would it be helpful/strengthening to add references on how much the dependence of imported sperm is (and consequently how much international regulation is needed?) eg Artificial insemination with donor sperm (AID): heterogeneity in sperm banking facilities in a single country (Belgium) A. Thijssen, N. Dhont, E. VanDormael, A. Cox, E. Klerkx, E. Creemers, W. Ombelet. FVV in obG yn , 2014, 6 (2): 57-67. Numbers of NL and UK should be available as well.	Thank you for this comment. We have added a reference to the paper you provided.
52	Astrid Indekeu		1	16	Maybe add (regarding the case of Jonathan Meijer) ‘via donations to several clinics, sperm banks and private donations’ (this is not only due to private donations, and clarifies the importance of a signed declaration, with possible legal consequences?)	This was adapted as suggested.
53	Astrid Indekeu		1	17	Maybe add ‘and where national donor limit was breached’ (as -with the current suggestion of 50 families, 67 children can also be easily conceived) --- so it is not only the large number of offspring but also a lack of regulation, (legal?) control	Thank you. The number was updated to 197 in line with more recent news coverage.
54	Fertility Europe			272-276	Reference 22 and the text in the draft should be updated as we now know that at least 200 children may have been affected in many European countries, not only Belgium	This was adapted as suggested.
55	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		1	14-18	This is missing information regarding sperm donors who have sought parental rights through the family courts.	These cases were not included because there is no direct link to the topic of offspring limits
56	Donor Conceived UK		1	11	RE Language: Donor Conceived People (DCP) is the preferred descriptor/ acronym	This was adapted as suggested.

57	Donor Conceived UK			52, 201, 214	RE Language: ‘...access to identifying information on their PARENTS donor...’ (Donation was made to parents not DCP).	Thank you. While the working group fully agrees with this comment, there was a concern that using "their parents' donor" may create confusion and lead to the impression that the text is referring to cases where the parents are also donor-conceived. Instead, the wording was changed to "the donor" throughout the paper.
58	Fertility Europe	Factual, neutral language			We appreciate care that ESHRE put in selecting the most factual and neutral language. We suggest where possible avoiding the word ‘sibling’ and using instead ‘donor-conceived people from the same donor’.	Thank you. Given the length of the term "donor-conceived people from the same donor", this change would make it more difficult to read the text. The term "donor siblings" is widely used and often chosen as the preferred term by donor-conceived people. Therefore, it was decided to keep it in this paper.
59	CRYOGONIA CRYOPRESERVATION BANK		1	27	The notion of the donors and recipients supporting the term 'donor' is realistic and depicts the actual status of donation. Gamete donation is not intended to create extended families connected by biological provenance. It is a method of medically assisted creation of offspring to individuals who cannot achieve it via natural or assisted conception by their own gametes.	Thank you for sharing your position.
60	Aoife Campbell		1	29-30	I agree with the use of these terms as the most widely understood	Thank you.
61	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		1	24-32	Language refers to relationships - donor conceived people may recognise as ‘Donor Dad’ as the relationship of donor is between the adults making the arrangement, directly, or through a clinic.	Thank you for this explanation.
Psychosocial aspects						
62	Viville Stéphane		1	37	“direct to consumer genetic testing” should be define (glossary?)	Thank you. This was added as suggested.

63	Anonymous	Psychosocial aspects			It seems that the remarks about psychosocial aspects are addressing points made by some DCPs who want to seek contact and establish relationships with donor siblings. All DCPs with a different view are ignored and they will indirectly suffer the consequences. Not only is the harm unclear, but also the number of people claiming to experience this harm is unclear. The suggestion now is that this is widespread but these points really need more clarification and evidence. How many suffer and is it more than being distressed? Because some are distressed by being donor-conceived too.	Thank you. The text explicitly states that not all donor-conceived people are interested in a relationship with donor siblings. The working group acknowledges that there is a lack of hard evidence, but considers that the current evidence is sufficient to call for a precautionary approach.
64	European Society of Human Genetics (ESHG)	Psychosocial aspects			The consideration of the psychosocial aspects pertaining to conceived individuals and donors is commendable. This would seem the most elaborated part of the document.	Thank you.
65	The Danish Business Association for Egg and Sperm Donation (BFSD)	On psychosocial considerations			We acknowledge ESHRE's emphasis on psychosocial aspects, including feelings of overwhelm or uncertainty among some donor-conceived people when large sibling groups are discovered. These experiences must be taken seriously. At the same time, it is important to recognise that donor-conceived people have diverse views and preferences. Not all wish to engage with donor siblings or donors, and not all experience large sibling numbers negatively. On the contrary, some donor-conceived children thrive in the knowledge that they have many siblings with different backgrounds and feel this has enriched their lives. It is imperative to ensure a balanced dialogue on these factors, representing all views. This balance has not been presented in the current debate. The focus has been overwhelmingly on requiring "local donations exclusively for local citizens". In addition to inevitably causing shortages in "local-only" countries, such an approach would limit access to donors for patients in countries lacking adequate infrastructure and resources. A "local-only" approach will further increase fertility tourism (achieving the opposite of	The position paper explicitly mentions that not all donor-conceived people are interested in a relationship with donor siblings. It also acknowledges that contact with donor siblings is often perceived as positive and rewarding. Moreover, the text does not call for a "local-only" approach. It states "ESHRE is not in favour of restricting the cross-border exchange of gametes. Particularly within the EU, where people, services and goods can move freely between countries, we call for a harmonised EU-wide framework rather than focusing on national borders."

					what was intended), and this narrow focus (distributing a donor's sperm in a small geography with a homogeneous population) will potentially increase the consanguinity risk but is also a potentially dangerous proposition as relates to acceptance of population diversity and multicultural values. Regulation should therefore aim to reduce uncertainty and extremes, rather than attempt to shape personal relationships or expectations, or to act politically as a means of population homogeneity planning.	
66	Astrid Indekeu		1	37	Maybe add reference (Indekeu, A., Maas, A., McCormick, E., Benward, J., Scheib, J. (2021). Factors associated with searching for people related through donor conception among donor-conceived people, parents and donors: a systematic review. F & S Reviews, 2 (2), 93-119. doi: 10.1016/j.xfnr.2021.01.003) for an overview of different reasons for why donor-siblings are important as mentioned in different studies	Thank you, the reference was added.
67	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		2	39	Contact between donor siblings is not always or “often perceived as positive and rewarding.”	The text does not state that this is always the case. Since positive experiences are mentioned in a high number of papers, the working paper considers the statement that this is often the case substantiated.
68	Cryos International Sperm & Egg bank		1	36-39	The text explicitly acknowledges that not all donor-conceived people are interested in a relationship with donor siblings.	Thank you, the references were reviewed and most of them were added to the paper.
69	Cryos International Sperm & Egg bank		1	39-41	In Persaud et al., (DOI link) most participants described feeling ‘neutral’ about the idea of donor siblings, in relation to when their differences from other people were accentuated. This highlights the need for psychosocial counselling for donor-conceived individuals, regardless of whether they have linked with donor siblings.	Thank you for sharing these insights.
70	Paths to Parenthood		1	40	While the ESHRE draft report focuses on the psychosocial challenges faced by donor conceived people when connecting with donor siblings in	Thank you for sharing these interesting insights. For reasons of transparency, we only cite resources that are publicly

				<p>adulthood, our experience through the support platform highlights an important and emerging trend earlier in family life. Increasingly, parents of donor conceived children are actively seeking to identify, and in many cases initiate contact with other families who have used the same donor before their children reach the age of 18. Feedback from our community indicates that many parents feel insufficiently supported in this process and lack the knowledge, guidance, and practical skills needed to navigate these relationships. This uncertainty is often compounded when parents discover that the number of donor siblings is larger than anticipated, or potentially very high, which can significantly increase feelings of overwhelm and anxiety. As a result, parents may feel unsure about whether to seek out donor siblings at all, and if they do, how to approach these connections in a way that best supports their children and all families involved.</p> <p>In support of these observations, here at Paths to Parenthood we recently launched our BIG Donor Conception Survey*, gathering responses from intended parents, those undergoing treatment, and parents of donor conceived children. Of the 578 respondents to the ‘donor siblings’ section of the survey, when asked “If donor siblings exist or may exist, do you plan to help your child connect with them?”, 8% reported that they had already connected with their child’s donor siblings, and 19% said they intend to facilitate contact before their child turns 18.</p> <p>Furthermore, when asked “What concerns do you have about donor siblings?”, 62% selected “not knowing how many donor siblings exist”, and 46% selected “managing relationships with multiple families”, highlighting the significant emotional and practical challenges families face in the absence of clear limits, guidance, and support.</p>	<p>available in the position paper. Please feel free to share any publications on this survey with us when they are ready.</p>
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71	Leah Gilman		1	41	May want to flag that one reason this is difficult to navigate is that it often involves a donor conceived person – who knows they are donor conceived - being contacted by a donor sibling who does not know this. The decision as to whether and how to disclose this information is ethically and emotionally challenging (discussed in Gilman et al. 2024 paper already cited)	Thank you for this input. As it is describing a general challenge of contact between donor siblings, which is not directly related to donor sibling numbers, it was not included in the paper.
72	Astrid Indekeu		1	41	Please add reference 5 to 7 here (as now the paper is only mentioned L39) in positive was, but the paper especially also addresses the challenges	Thank you. The reference was now added in both places.
73	Cryos International Sperm & Egg bank		2, 5	44-45, 201-203	In this literature review of 499 records (link), we found no indications of concerns (or positive views) regarding age gaps between donor siblings or their potential implications. Further research should be done to explore this aspect of donor conception to ensure an evidence-based approach to practice.	Thank you. The working group acknowledges that there is a lack of hard evidence on concerns of donor-conceived people regarding age gaps. However, concerns have been raised in grey literature as well as in many of the stakeholder comments.
74	Menno Hofman		2	44	Even without age gaps due to cryopreservation, age gaps can easily be 15 years or so. Like I became a sperm donor when I was 18. I was 35 when my wife and I had our 1 st child. While putting a restriction on cryopreservation makes sense, it is also important to inform recipients that such age gaps can exist, also between their child(ren) and those of the donor. Long cryopreservation has another problem: the donor will get older. Chances that the donor conceived will not be able to have contact with the donor will therefore increase.	Thank you for sharing your personal insights. The issue of donors getting older with long cryostorage is addressed in the section on contact between donor and offspring. Counselling of recipients is considered outside of the scope of this paper.
75	CRYOGONIA CRYOPRESERVATION BANK		2	48	Yet again, another misconception regarding the purpose of gamete donation. Each family created by donation is a separate entity, not socially linked to other families merely by common biological provenance. In fact, there are many families created by donation who do not wish to establish a connection with other same-donor conceived families. The vast majority of heterosexual couple-recipients do not even intend to disclose the donation process to their children.	Thank you. The paper acknowledges that not all donor-conceived people are interested in contact with donor siblings. Nonetheless, there are several accounts that many donor-conceived people are interested in their genetic connections and the working group considers it important to account for the interests of this group.

76	Leah Gilman		2	48	You may want to highlight that this is likely to be particularly pronounced where it is associated with language barriers.	Thank you. This aspect was added to the paper.
77	Astrid Indekeu		2	49	The challenges of creating kinship – see Bolt, S.H., Notermans, C., van Brouwershaven, A., Maas, A.J.B.M., & Indekeu, A. (2021) The ongoing work of kinship among donor half-siblings in the Netherlands. Biosocieties. doi:10.1057/s41292-021-00259-z	Thank you. The reference was added.
78	CRYOGONIA CRYOPRESERVATION BANK		2	50	Access to donor identity should by no means be interpreted as possibility or feasibility of contact with the donor. Local legislations in some countries, permitting ID-Release donation, limit the possibility of access only to the name of the donor. Again, this reasoning is derived from the misconception that donor conception is the way of creating extended family relations.	Thank you. While contact with the donor is indeed not always possible or feasible, access to donor identity does make it easier for donor-conceived people to contact donors. Therefore, no changes to the paper are considered necessary.
79	Cryos International Sperm & Egg bank		2	50	We acknowledge that multiple perspectives warrant consideration in this matter, and we believe there may be even more. For some donor-conceived individuals, connecting with donor siblings may represent an alternative way to learn about their genetic heritage if the donor is unavailable (e.g., deceased, anonymous, or unwilling to engage), and in some cases, this may even be preferred over contact with the donor himself. In Scheib et al., (DOI link), a donor-conceived individual stated that connecting with someone who shared the donor, rather than with the donor himself, might be more rewarding and less risky, describing this connection as ‘more of a reciprocal relationship’. Nelson, Hertz & Kramer, 2023 (DOI link) found that, among donor-conceived offspring, attitudes toward donor siblings tended to be more enthusiastic than toward donors. For three donor-conceived individuals in Persaud et al., (DOI link), finding donor siblings provided them with someone who could fulfil a perceived ‘missing’ role in their family.	Thank you. The importance of contact with donor siblings for some donor-conceived people is elaborated on in the section on contact between donor siblings.

80	Anonymous	Contact donor and offspring			This whole paragraph is largely speculation. If an argument like this is made, the least one can do is provide evidence in the form of references.	Thank you. A paragraph was added to the paper to acknowledge the lack of evidence on psychosocial aspects more explicitly and explain that also potential risks that have not yet been widely studied are taken into account, since there is also no reassuring evidence that these risks do not materialise in practice.
81	Astrid Indekeu		2	54	Maybe also add: Crawshaw, M., Daniels, K., Adams, D., Bourne, K., van Hooff, J. A. P., Kramer, W., Pasch, L., & Thorn, P. (2016a). Emerging models for facilitating contact between people genetically related through donor conception: A preliminary analysis and discussion. <i>Reproductive Biomedicine & Society Online</i> , 1(2), 71–80. https://doi.org/10.1016/j.rbms.2015.10.001 Showing all the different possibilities to get in contact with each other	Thank you. The reference was added.
82	Marilyn Crawshaw		2	54 & 57	Suggest you delete (ongoing) so that the fact of making contact is standalone. Then I suggest you amend line 57 to something like ‘... invest in an ongoing relationship if desired’.	This was adapted as suggested.
83	Cryos International Sperm & Egg bank		2	59	While it is assumed that donors might be concerned about the impact of large offspring numbers on their own children, our recent study (Lassen et al. 2024. Four decades of sperm donation: motivation and attitudes among donors: DOI link) provides more nuanced insight. Among donors, only 21% stated they would not tell their current or potential future children about their donation, whereas 63% indicated they would, suggesting a general openness toward donation and its implications for their families.	Thank you. We consider that the fact that donors are open to their own children about their donations does not necessarily imply that donors have no concerns over the impacts of large donor sibling numbers on their own children.
84	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		2	60	We agree that there is a lack of research in this field and strongly suggest that gap-fill research should be commissioned prior to suggestions being proposed on limits and regulation.	Thank you for sharing your position. However, the working group considers it relevant to take a precautionary approach in the absence of conclusive

						research, rather than delaying the introduction of limits and regulation.
85	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		2	60-64	Geographical distance may be preferred by recipients: "the recipient family may be perceived as beneficial to preserve the family unit". This suggests a prioritisation of adults and a deprioritisation of children as children not raised by their genetic parents are more likely to experience genealogical bewilderment. This suggests bias in approach.	The fact that the position paper also mentions the potential interests of parents does not mean that the interests of children are deprioritised. The position paper aims to take the interests of all parties into account.
86	Cryos International Sperm & Egg bank		2	60-61	<p>We would like to emphasize that donors enter into an agreement with Cryos with the explicit understanding that their gametes will be distributed worldwide for fertility treatments. Donors are furthermore fully informed about the collection, use, and disclosure of their personal data in this context.</p> <p>For ID-release donors, we ensure that they are aware of and consent where required to the sharing of their personal information with clinics, authorities, and donor-conceived individuals in other countries, in accordance with local legislation and to the extent required.</p> <p>Based on our experience, Cryos does not observe that donors refrain from donating due to the fact that their gametes and personal data may be distributed internationally. On the contrary, donors accept this as part of the donation process and the global nature of assisted reproduction services.</p> <p>To contribute to evidence-based research in the field, we are currently conducting a study in which Cryos' donors are asked to rate various statements regarding their donations. Of 274 respondents, the majority (54%) have stated that they 'neither agree or disagree' on the statement 'I hope that the children, born from my donations, live far away from me', while 26% either disagree or strongly disagree and 17.8% either agree or strongly agree (Unpublished data, manuscript in preparation).</p>	Thank you for sharing these insights.

87	Michael Scholtes	Psychological aspects 60			Donors should indicate a limit on the number of offspring/ families to be treated. International donor registration should enable donors to be informed about the number of offspring, although not provide data about the individuals. Donor banks should be regulated by legislation to respect the imposed limit.	Thank you. All of these points were already included in the paper.
88	The Danish Business Association for Egg and Sperm Donation (BFSD)	The need for clarity and harmonisation			BFSD agrees with ESHRE that the lack of an EU-wide limit can create uncertainty for all parties involved. As stakeholders, we believe it is essential to create clarity and predictability, enabling informed choices and consistent standards across Europe. However, clarity must also include a shared understanding of what a donor is — and is not. Gamete donation was never intended to establish extended family structures or social sibling networks. While we fully respect that some donor-conceived individuals wish to establish a relationship with donors later in life, this was never the intention of donation — nor was the creation of relationships between donorconceived offspring. Conflating genetic connection with social or familial roles risks misunderstanding the nature of donation and may unintentionally reinforce perceptions of commodification that the regulation seeks to avoid. A donor is typically a young man early in life, who volunteers to assist people in need by providing a biological sample. A donor is not a father and should have no implied or actual responsibilities because of this important contribution to helping people create the family they dream of. If these parameters change, we believe fewer men will choose to become donors. ESHRE, authorities, and all relevant stakeholders must ensure that this balance is maintained, and that donors' rights to privacy are fully protected.	Thank you. It is not the intention of the paper to imply that donors should take on a parental role. However, we do consider it necessary to account for the reality that many donor-conceived people find these genetic connections important and seek contact.

89	Cryos International Sperm & Egg bank		2	67-69	<p>We have conducted a qualitative study of former Danish sperm donors more than 10 years post-donation (Lou et al. 2023 Experiences and attitudes of Danish men who were sperm donors more than 10 years ago; a qualitative interview study: DOI link) that showed that most donors viewed their donation as a “closed chapter” and did not experience ongoing implications in their current lives.</p> <p>A few, however, continued to think about potential offspring contact. Donors were generally satisfied with their original choice of anonymity level and emphasized maintaining contractual rights and obligations. While informed at the time about possible breaches of anonymity in the future, most did not worry about it and had not planned for offspring contact. Currently, all sperm and egg donors at Cryos undergo psychological evaluation by a psychologist, including assessment of their understanding of future implications. The psychologist may reject candidate donors who are not prepared for these potential long-term consequences.</p>	Thank you for sharing these insights.
90	Viville Stéphane		2	69	In France the legislation on private life does not allow to contact some one	Thank you for sharing these insights on your national rules in France. Since these rules are not in place in all countries, we still consider this point relevant.
91	Donor Conception Network		2	67-71	<p>Uncertainty</p> <p>We would ADD uncertainty for parents.</p> <p>They are the ones making decisions and they need to be aware of the limits and the manner and precision with which they are upheld. They will be sharing this information with their child and need to be sure they are sharing accurate information, building trust and ensuring DCPs are not blindsided by unexpected revelations.</p>	Thank you. This aspect was added to the paper.
92	Stop Surrogacy Now UK (Lexi Ellingsworth) and		2	67	Uncertainty does not necessarily apply to all parties, adults who donate will know which countries they have travelled to and donated in and prolific, serial sperm	Thank you. Indeed, sperm donors know which countries they have travelled to, but they are not always aware of the

	Surrogacy Concern (Helen Gibson)				donors have been known to proudly share numbers of children as well as conceal and deceive on the total number of children born from their donations. This has been explored in mainstream media and national and international press. Attitudes of sperm donors can be rooted in deeply misogynistic and supposedly philanthropic motivations	extent of use of their gametes by gamete banks.
93	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)	Identity release and DNA Testing			This position paper acknowledges the practical implications for donor conceived people obtaining information about their genetic roots but it does not discuss the financial costs involved, nor does it explore the mental load and emotional labour associated with these circumstances of being. Sharing your DNA for third party testing for the purposes of finding a genetic family requires disclosure of a deeply personal sensitive nature, entering into their terms and conditions and paying the required fees. Additional fees may be required if a donor conceived person decides to engage with a private detective in order to track down family members. There is a heavy financial and emotional burden on donor conceived people regarding these two areas that people who are raised with their natural, genetic parents, do not have to engage in.	Thank you. General considerations on donor conception and access to the donor identity are considered outside of the scope of this paper.
94	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)	Contact and Mental Health Support			The International Infertility Counselling Organisation (IICO) also draws attention to this crisis situation in its 2024 statement and calls on treatment providers to take responsibility: <i>“The fertility industry should share responsibility for the provision of high quality psychosocial professional support services. This field is ever evolving but the barriers to responding organically throughout the life stages with appropriate psychosocial skills and knowledge include the lack of financial structures and policies as well as the limited research and practice evidence base and the limited availability of training, in particular for work at later life stages.”</i> We observe the lack of exploration of the associated	Thank you. This position paper is on donor offspring limits, so we consider counselling outside of the scope. Please check the ESHRE Good Practice Recommendations on information provision for those involved in reproductive donation for recommendations on counselling for donor-conceived people.

				<p>mental health support for those who find themselves as one of a large ‘sibling pod’</p> <p>2023 was the first year that donor conceived children in the UK could obtain fully identifying details for their genetic parents. By the end of 2024 766 were eligible to access this information and by 2030, Human Fertilisation and Embryology Authority (HFEA) reports that 11,427 adults will be eligible.</p> <p>A 2021 study explored the feelings of 143 individuals who were donor-conceived.</p> <ul style="list-style-type: none"> ● 85% reported a shift in their “sense of self” upon learning about the nature of their conception and about half sought psychological help in order to cope ● 74% said that they often or very often think about the nature of their conception ● 62% felt the exchange of money for donor gametes was wrong ● Almost 43% believed that genetic testing companies ought to offer more complete information about using their products ● 90% believed being fully informed was impossible <p>This is a rare opportunity to consider the donor conceived people who are born as a result of the Fertility Industry and we note the lack of exploration of provision for those who are already born, who already exist and who have participated in their review. Counselling is not out of scope of this position paper and we expected to see more on this area of donor conception practices in order to ‘future-proof’ this industry for the children at the centre</p>	
95	Annemieke Hoek	Sense of commodification		<p>The ESHRE statement should more elaborate on this part: large gamete banks operate like businesses, are owned by private equity organizations, sell gametes as “IUI ready products”/ services/ higher prices are involved for recipients. In case the want to know more about the donor profiles. Donor banks offer service of donor exclusivity, if the recipients are willing to pay more.</p>	<p>Thank you. The working group considers the overall commercialisation of gamete banking to be a separate point that is not strictly linked to offspring numbers, which is why it was not added to this paper.</p>

					It is clear that commodification of donor gametes is at hand, as ESHRE members we need to speak up about this commodification of reproduction.	
96	Stichting Donorkind	Sense of commodification			<p>The ESHRE statement should more elaborate on this part: large gamete banks operate like businesses, are owned by private equity organizations, sell gametes as “IUI ready products”/ services/ higher prices are involved for recipients In case the want to know more about the donor profiles. Donor banks offer service of donor exclusivity, if the recipients are willing to pay more.</p> <p>Extra profits are made by selling information of donors to parents, like letters, voice recordings and childhood-photo’s of the donor. Als this information falls clearly within the “the right of identity” under Articles 8 of the European Human Rights and art. 8 of International convention on the Right of the Child.</p> <p>This is the commodification of people and the exploitation of peoples personal information and origin.</p>	Thank you. The working group considers the overall commercialisation of gamete banking to be a separate point that is not strictly linked to offspring numbers, which is why it was not added to this paper.
97	Cryos International Sperm & Egg bank		2	72-73	<p>We found no clear evidence of feelings related to perceptions of being ‘mass-produced’ in our literature review of 499 records (L Sophie Sørensen, et al., Donor-conceived persons’ experiences of (possibly) having multiple donor half-siblings: A systematic literature review and thematic synthesis: link).</p> <p>Further research should be done to explore this aspect of donor conception to ensure a comprehensive and representative understanding.</p> <p>In our recent study (Lassen et al. 2024) we found a generally positive orientation among donors: 40% wished to know how many children had been conceived from their donation. Additionally, 58% reported feeling happy when thinking about their donor offspring, 30% said the donation did not influence them, and none reported feeling sad about their donation.</p>	Thank you. The working group acknowledges that there is a lack of hard evidence on feelings of commodification among donor-conceived people. However, concerns have been raised in grey literature as well as in some of the stakeholder comments.

98	Association of Reproductive and Clinical Scientists (UK)	Donor voice			ARCS have recently run events where representatives of Donor Conceived UK (a charity focusing on donor conceived offspring), who have clearly stated that unlimited donation has significant potential to cause harm.	Thank you.
99	Association of Reproductive and Clinical Scientists (UK)	Lack of clear research			It would be good to see some research into how donor conceived individuals relate to the number of families specifically. We believe that this could be a strong priority topic for an ESHRE research grant.	Thank you for this suggestion.
100	Institute of Advanced Training and Family Psychotherapy, Florence	Psychosocial aspects			After paragraph 73 I would add the following part: “Psychological support: Given the variety of emotional, relational, and identity-related challenges that may arise for donors, parents, and donor-conceived people — both at the time of donation and throughout the life course — it would be beneficial for specialized psychological counselling to be routinely available in all European countries. Importantly, such support should not be limited to the decision-making stage or to the treatment process; it should also be accessible after the birth of the child and at later developmental stages. Continuous psychological support can help parents navigate disclosure and family communication, assist donors in processing the long-term implications of their donation, and provide donor-conceived people with an appropriate space to address questions or concerns that may emerge over time.”	Thank you for this suggestion. The working group acknowledges the importance of psychological support, but considers that this topic is outside the scope of this paper.
Access to treatments with donor gametes						
101	Human Fertilisation and Embryology Authority (HFEA)				We acknowledge the concerns raised in the section Access to treatments with donor gametes. If any international or European limit were to be developed in the future, we would support efforts to ensure that these concerns are fully considered. It would also be important that the views and experiences of donor-conceived people, donors and recipients are taken into account.	Thank you.

102	European Society of Human Genetics (ESHG)	Access to treatments with donor gametes			<p>This is one of the key elements. It would be helpful to provide some numbers related to existing practices and/or references?</p> <p>The text asserts that “unless donor recruitment can be increased quickly and substantially, patients will likely have to wait longer...” This is not justify why recruitment cannot scale. So evidence is needed: historical donor recruitment trends, international comparisons, behavioural data, or modelling. Without this, the argument rests on a speculative premise.</p>	<p>The evidence requested here is unfortunately not available. This is why the paper proposes a precautionary approach where international limits are implemented gradually alongside a monitoring of the impacts.</p>
103	Lisa Ransome	Access to treatments with donor gametes			<p>The utilization of the argument, reducing donor limits reduces donors, has been shown overall to not be true. While in the short term there is likely to be implications on the number of recipient families from donor limits, there is also the potential more people will be open to becoming donors due to the enforcement of donor family limits in the medium to long term.</p> <p>Additionally, those who are wishing to become donors, need to also be transparently counselled they are able to select a LOWER number than the EU/International limits stipulate.</p> <p>While the cost argument is also utilized as an impacting reason for not reducing the family limits, there are many countries where payment to donors cannot be beyond compensation/reimbursement (UK, Australia & NZ). If a compensation model was employed with a standardised amount (similar to HFEA setting of payment limit) within the EU, and more broadly, then the increasing costs of using donor gametes could continued to be limit for those family needing to access for family building purposes.</p> <p>This would also potentially reduce the noted expression of commodification from those who are donor conceived where so called “sought after” genetics, appearance and/or IQ are not paid for in greater sums, than beyond appropriately reimbursement for time and physical impact (in the case of oocyte donors).</p>	<p>We could not find any evidence for your statement that the argument has shown overall not to be true. In the EU, all donations need to adhere to the principle of voluntary unpaid donation. However, higher costs are not primarily expected due to higher donor compensation, but due to the costs of donor recruitment and screening being distributed over fewer recipients.</p>

104	Michael Scholtes	Psychological aspects 74			<p>The well-being of donor conceived offspring should be #1, regardless a possible shortage, no compromise is possible here. The authorities of all European governments will have to implement regulations how to compensate donors. This will have to be on a national level.</p> <p>The ESHRE has to take an official position how to implement an acceptable regulation of the donor market and cannot accept responsibility for all kinds of donations outside of the official, accepted system</p>	Thank you. However, the working group considers that it is important to take the implications for all parties into account and to propose a balanced approach.
105	Board of Health and Welfare (Sweden)		2	75	<p>A lower limit might make potential donors more likely to donate. In Sweden, we have been told that the frequent media coverage of misconduct regarding donation of gametes (a lot of half-siblings, no control of number of children across the world) has made some donors hesitate. So, more control and a lower limit can potentially lead to an increase in the number of donors</p>	Thank you. The fact that the absence of limits can raise concerns of donors is mentioned in the section on contact between donors and offspring. No specific evidence on an increased number of people being willing to donate gametes in the presence of lower limits was found, so this aspect was not added explicitly to the paper.
106	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		3	75-78	<p>“unless donor recruitment can be increased quickly and substantially, parents will likely have to wait longer until they can get access to donor gametes, or they may not be able to access donor gametes at all.”</p> <p>Lack of access to gametes for recipients appears to be instigating the proposal of a 50 family limit which goes beyond any country limit to a factor of roughly 5. Increased costs due to a ‘shortage’ or donors and longer wait times are recipient-lead arguments. The proposals appear to expand and perpetuate donor conception, rather than adequately review the impact, despite acknowledging the likely impact on children. We note the very short acknowledgement of feeling of commodification in two lines (72-73).</p>	Thank you. Indeed, the working group considers that it is important to take the implications for all parties into account and to propose a balanced approach. Please note that the proposal does not expand donor conception. It proposes the introduction of new regulations where currently no regulations are in place at all.
107	Aoife Campbell		2	79-80	<p>This may be true, but I suggest the profit margins currently enjoyed by some Donor Banks could withstand being reduced while remaining profitable business.</p>	Thank you. The working group considers that price regulations for gamete banks are outside of the scope of this position paper.

108	Viville Stéphane		2	81	“costs will exacerbate inequality” unless funding policies put in place	Thank you. This aspect was added to the paper.
109	Paths to ParentHub		2	78	<p>As an organisation that supports individuals and families using donor conception, access to donor gametes, both financially and practically - is a key concern for our community. Many intended parents we support report significant difficulties in finding suitable donors, particularly those from ethnically diverse backgrounds. At Paths to ParentHub, we would strongly welcome an active and sustained donor recruitment strategy to address these disparities.</p> <p>We recognise that introducing lower limits on the number of families per donor may raise concerns about potential supply constraints. However, we believe these risks can and should be mitigated through proactive donor recruitment efforts. It is also important to consider that clearer and more ethically grounded limits may, in fact, encourage more individuals to donate, particularly those who are reassured that their donations will not be used to create an excessive number of families.</p> <p>Additionally, while concerns are often raised (mostly by gamete banks) about the potential for increased costs, is there any evidence that reduced family limits would necessarily lead to higher prices for patients? Is it equally possible that such changes would primarily impact the profit margins of private, shareholder owned gamete banks rather than affordability or access for families. Careful monitoring and transparency around pricing would therefore be essential as limits are introduced to see what the real time impact is on the individual or couple using donor gametes.</p> <p>At Paths to ParentHub, we have been fortunate to work closely with a number of gamete banks both in the UK and internationally. The banks we have engaged with are able to offer a diverse range of donors at competitive costs while also operating with low, self</p>	<p>Thank you for sharing these insights. Indeed, smaller local banks often manage to operate with low self-imposed limits in place. However, such banks are not in place everywhere across Europe and current gamete supply relies heavily on big international banks with high self-imposed limits or no limits at all, which is why the working group considers a gradual approach necessary.</p>

					imposed family limits, often capped at 10 families or fewer internationally. Importantly, many of these banks achieve this while complying with stringent and often costly regulatory requirements. This raises a critical question: if these practices are demonstrably achievable within existing regulatory and financial frameworks, why are other gamete banks unable or unwilling, to adopt similar limits?	
110	Cryos International Sperm & Egg bank		2	75-78	<p>We anticipate the same outcome: implementing international limits will reduce the number of families per donor and could lead to longer waiting times and/or limited access unless donor recruitment increases significantly.</p> <p>Another unavoidable consequence is higher prices for donor gametes due to basic supply-and-demand dynamics. This risks creating a socioeconomic divide in who can access treatment, pushing individuals with lower income toward unregulated or unsafe options on the unregulated market.</p>	Thank you for sharing your views.
111	CRYOGONIA CRYOPRESERVATION BANK		2	75-78	This is indeed a grave problem considering the very low acceptance rate of donors due to the strict selection process (2-8%). Also, due to the continuously decreasing semen quality, this poses a very difficult task.	Thank you for sharing your views.
112	Donor Conceived UK		2-3	74-87	<p>In the section headed ‘access to treatments’, it is also important to recognise that greater clarity and consistency around limits can have a positive impact for prospective recipients themselves. Clear, internationally applicable limits can provide reassurance and peace of mind about how many Donor Conceived People (DCP) may be created from the same donor.</p> <p>Evidence suggests that some UK parents continue to believe that the UK’s ten-family limit is an absolute cap, even when they have been informed that this limit applies only within the UK and not to imported gametes. There have also been recent reports of UK solo mothers who were unaware that their UK donor’s</p>	Thank you for raising this point. The uncertainty for parents was added in the section on uncertainty.

					sperm had been exported for use abroad. Being able to refer to transparent, internationally recognised limits at the outset of treatment would therefore support informed decision-making, reduce misunderstanding, and help prospective recipients better understand the potential size of donor sibling groups alongside strengthening trust in regulated donation systems.	
113	Marilyn Crawshaw		2-3		In the section headed 'access to treatments....' Maybe it's also worth adding that a positive impact is that some prospective recipients will benefit as a result of more clarity and peace of mind about how many other DCP will be created. There's evidence that some UK parents still think the 10 family limit is an absolute one even if they've been told prior to treatment that the imported gametes only applies to UK; and there was recent report of UK solo mums who were unaware that their UK donor's sperm had been exported. So being able to refer to international limits at the outset should help.	Thank you for raising this point. The uncertainty for parents was added in the section on uncertainty.
114	Viville Stéphane		2	83	"private donations" should be defined (glossary?)	The text already specifies that this refers to donation outside of gamete banks and fertility clinics, so we do not consider any further definition of the term necessary.
115	Board of Health and Welfare (Sweden)		2	82	Perhaps we could have a recommendation that MS should inform of the dangers of these private arrangements? There are serious legal repercussions both for both recipients and donors	The text already specifies that "Efforts should be made [...] to avoid that patients move to unregulated private donations." Specific recommendations on patient information are considered outside of the scope of this paper.
Genetic aspects						
116	Marilyn Crawshaw		3	90	I think you mean romantic and/or sexual? Not all sexual relationships are romantic and wv!	Thank you. This was adapted as suggested.
117	Viville Stéphane		3	94	No more recent reference then 13?	We consider that the reference provided is still valid, as the results of mathematical modelling of the risk of

						consanguinity are not likely to change within a short period of time.
118	Viville Stéphane		3	88-97	Only one reference here. Naything else. It is a bit limited	The reference included provides a literature review of several studies, and we consider it provides sufficient evidence for the claims in the paper.
119	The Danish Business Association for Egg and Sperm Donation (BFSD)	Genetic considerations should not drive donor limits			BFSD strongly agrees with ESHRE's conclusion that genetic arguments should not be considered a valid basis for determining donor offspring limits. Firstly, consanguinity between donor-conceived people is identified as a very low risk – which with openness of donor ID will probably be even further decreased. Secondly, the propagation of genetic diseases is not correlated with the number of offspring per donor, and donor-conceived people are often subject to more extensive genetic screening than the general population and therefore the risk of genetic conditions is actually lower for donor-conceived people than for others. We believe these points are crucial and should be communicated clearly in public and political discussions, as genetic risk is frequently — and incorrectly — used to justify restrictive limits.	Thank you.
120	CRYOGONIA CRYOPRESERVATION BANK		3	96	Very true. According to a French study by <i>Serre at al</i> , the possibility of unintentional unions between false paternity offspring are roughly four times more frequent than those resulting from anonymous donation. [Serre JL, Leutenegger A-L, Bernheim A, et al. Does anonymous sperm donation increase the risk for unions between relatives and the incidence of autosomal recessive diseases due to consanguinity? Hum Reprod (2014) Vol.29 No.3 pp.394–399 doi:10.1093/humrep/det452]	Thank you. This study is included in the literature review that is cited in the paper.
121	Lisa Ransome	Consanguinity			While the risk of consanguinity is seen to be a low risk, even at present with the current no-limit posed functioning of donor banks, there continues to be a perceived risk within the general populace, and concerns raised from those people who are donor	Thank you. The fear of consanguinity experienced by donor-conceived people was added to the paper, in the section on uncertainty.

					conceived. While many of the concerns are raised from those who have been conceived through treatments where unethical practices have occurred (e.g. fertility specialists historically exchanging their own sperm for the selected donor, in the case of Jan Karbaat (Netherlands), Donald Kline (USA), or prolific sperm donors such as Jonathan Jacob Meijer). The risk of consanguinity remains a risk if there is no limit to the number of recipient families, combined with sperm/oocytes being utilized in a small geographic area.	
122	Donor Conceived UK		3	91-97	<p>RE Consanguinity: While Donor Conceived UK recognises that some studies have modelled a statistically low risk of consanguinity, we strongly disagree with the assertion that consanguinity is “no longer such a pressing concern.”</p> <p>This conclusion rests on assumptions that do not reflect current legal or social realities. Crucially, there is no legal requirement in the UK for parents to disclose to a child that they are donor conceived. As a result, it is not known how many Donor Conceived People (DCP) are aware of their conception status, and many reach adulthood without this knowledge. Where disclosure does not occur, Donor Conceived People (DCP) cannot take steps to avoid relationships with genetic relatives, regardless of donor limits, openness norms, or the availability of genetic testing.</p> <p>Furthermore, reliance on “increasing openness” and consumer genetic testing shifts responsibility away from regulators and onto individuals often without their informed consent. Genetic testing is neither universal nor foolproof, and many people do not test until later in life, if at all. Openness by donors to their own children is also voluntary and inconsistent.</p> <p>In this context, consanguinity remains a live and legitimate concern, particularly when combined with:</p> <ul style="list-style-type: none"> • incomplete or absent disclosure, • cross-border and international use of gametes, 	Thank you. The studies modelling the risk of consanguinity included in the cited literature review already account for the fact that donor conception is not always disclosed and still find a very low risk of consanguinity.

					<ul style="list-style-type: none"> • inconsistent record-keeping and limits across jurisdictions, and • donor offspring limits that are high relative to population density. <p>Donor offspring limits should therefore not be dismissed as outdated. Instead, they must be considered alongside the realities of non-disclosure, fragmented regulation, and the lived experiences of Donor Conceived People (DCP), many of whom are navigating genetic relationships without full or accurate information.</p> <p>In addition, consanguinity concerns must extend beyond direct donor-offspring relationships, as first-cousin relationships created through large donor sibling networks carry a higher risk of genetic disorders, and the scale at which first cousins are unintentionally created through donor conception must also be taken into account when setting donor offspring limits</p>	
123	Board of Health and Welfare (Sweden)		3	91	<p>In Sweden, we have some concerns about this; a lot of Swedish women go to Denmark for treatment, and a lot of clinics in Sweden use sperm from Denmark, making the number of children from the same donor higher than the national limit. We also recently had media coverage of donor children going to the same schools and living on the same street, despite low numbers which indicates the risk might as evenly disseminated as one might expect.</p>	Thank you. The paper acknowledges that there is a small risk of consanguinity, especially at a local level. The considerations described in the paper focus on the introduction of international limits, whereas the situation described in the comment relates to the use of gametes in a single country, which could be addressed by strengthening monitoring and adherence to the national limit.
124	Marilyn Crawshaw		3	96-97	<p>You completely miss out FEAR of consanguinity here and it's important to acknowledge its presence. It's reported in research and also anecdotally in the grey literature. By not including it, you silence the concerns of DCP</p>	Thank you for raising this point. The fear of consanguinity was added to the section on uncertainty.
125	Leah Gilman		3	88	<p>Arguably, the risks associated with potential for consanguinity are not just about actual probabilities of this happening but the fear of it and the challenges this</p>	Thank you for raising this point. The fear of consanguinity was added to the section on uncertainty.

					might pose in negotiating sexual and romantic relationships.	
126	Paths to ParentHub			88	We would argue that the risks associated with consanguinity are not solely about the probability of this happening to a donor conceived person, but the perceived fear of this event taking place. This poses challenges for individuals when looking to navigate sexual and romantic relationships, and a challenge that some parents of donor conceived children are already beginning to consider when they are aware that their child may be part of a large donor sibling cohort internationally. For example, in our recent BIG Donor Conception Survey, one parent commented that within her small solo-mum friendship group, two of the parents had inadvertently used the same sperm donor (therefore their children were in fact half siblings). This fact was discovered only in conversation between the parents at a social gathering.	Thank you for raising this point. The fear of consanguinity was added to the section on uncertainty.
127	Cryos International Sperm & Egg bank		3	89-97	We fully acknowledge that the risk of romantic relationships between donor-conceived siblings is, in practice, very low due to modern technology and increased openness, including when donor-conceived people are informed of the donor number used for their conception. However, we are currently preparing a paper presenting results from Cryos sperm bank customers on attitudes toward donor limits. In this study (n = 559), the primary reason cited for introducing a limit was concern about donor siblings forming romantic relationships without knowing their genetic relation (33%). A secondary reason was discomfort with not knowing how many donor siblings a child may have (16%) (unpublished results, manuscript in preparation). These findings indicate that the risk of unintended romantic relationships remains a significant concern among recipients of donor gametes. Addressing this will require sustained efforts in communication, education, and transparency about	Thank you for raising this point. The fear of consanguinity was added to the section on uncertainty.

					donor-conception. As a gamete bank, we fully support initiatives that help increase awareness in these areas.	
128	Cryos International Sperm & Egg bank		3	96-97	We agree that consanguinity is no longer a pressing concern when setting limits on donor offspring.	Thank you for sharing your views.
129	Menno Hofman		3	89	Some of the donor conceived will become donor themselves (at the AUMC in the Netherlands at least 3 donors were donor conceived too). Some donor conceived will later in life need a donor. While being both donor and donor conceived or being recipient and donor conceived does not have to be a problem at all, it does require proper registration and being considered when thinking about consanguinity risks.	Thank you for sharing this point. The working group considers that the recommendations for donor registration also cover this case and that the implications for consanguinity do not alter the recommendations of the paper, so this aspect was not specifically added.
130	Laura Fernández Olmedilla	Donor offspring (lines 94-95)			In the case of donors who do not yet have children but express their desire to have them in the future, the possibility of a family of their own should be considered from the outset, reserving at least one family unit for this life project for the purposes of the calculation. In this way, the rights of both, those born through donation and the donors themselves would be protected.	Thank you. The limits proposed in the paper do not include the donor's own family in the count, so there is no need to reserve a family slot for the donor's own family.
131	JUAN JOSÉ GUILLÉN			96	While the proposal suggests that genetic testing mitigates consanguinity risks, this creates a false sense of security. Current expanded carrier screening (ECS) panels used in clinical practice are not universal across Europe and typically only target common mutations. Identifying rare pathogenic variants would require deep sequencing (WES or WGS), which is currently not standard due to high costs and the complexity of interpreting VUS. Furthermore, merely knowing one's status as donor-conceived is an insufficient safeguard; without a centralized registry or generalized pre-conception testing for the entire population, individuals lack the functional means to verify genetic compatibility with a partner before conception.	Thank you. The argument in the paper is that if two members of a couple know that they are donor-conceived, they can access genetic testing specifically to determine whether they are genetically related, not that everyone should assess general genetic compatibility through expanded carrier screening.

132	Lisa Ransome	Propagation of Genetic Diseases			Consent is provided regarding the inability to screen for all possible genetic disorders, and this in and of itself it not a reason to cap the number of recipient families. As is required from 2027 in the EU to screen for potentially life-threatening, disabling or incapacitating genetic conditions, this should also be strongly encouraged and implemented in non-EU countries who provide gamete donation as a treatment option. It is also noted at present, Australian fertility clinics currently complete genetic carrier screening for 3 three most common recessive genetic heritable disorders, as well as karyotype screening. Other genetic screening will vary between clinics.	Thank you for sharing these insights.
133	CRYOGONIA CRYOPRESERVATION BANK		3	104-107	The EU SoHO could establish a list of dominant inheritance genes that should be screened obligatorily. Also, the integration of genetic matching between donors and recipients for recessive genetic diseases should be encouraged at a larger scale, to minimize the expression of these diseases in the offspring.	Thank you for sharing these suggestions. Genetic screening requirements are considered outside the scope of this paper.
134	London Sperm Bank	Mitigation should focus on distribution control and speed of response			Beyond current genetic screening (including future Substances of Human Origin requirements), “prevention” of all genetic risk is not feasible; mitigation is the practical pathway. The key residual risk is how far a donor can be distributed before the first affected offspring is identified. Therefore, the most impactful mitigation lever is distribution control by gamete banks under regulatory oversight, alongside a rapid feedback loop from detection → review → donor hold/suspension.	Thank you for sharing these insights. The handling of cases after a genetic condition is detected is considered outside the scope of this paper.
135	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		3	106-107	“Potentially life-threatening, disabling or incapacitating genetic conditions with a significant prevalence in the donor population will become mandatory” under the Substances of Human Origin (SoHO) Regulation will not apply to the United Kingdom. A lack of health screening has already proved fatal for donor conceived children as a “A sperm donor who unknowingly harboured a genetic mutation that dramatically raises the risk of cancer has fathered at least 197 children	Thank you. The working group does not consider the restriction of exports necessary to mitigate genetic risks, as countries can set requirements on the gametes that they allow for import and, more generally, since donor conception is not associated with an increased genetic risk, as explained in the paper.

					across Europe, a major investigation has revealed.” (BBC December 2025). Higher, more involved levels of health screening for donor recipients will be expensive unless the cost of such tests is to be managed by the clinics without an adjustment to the gamete packages. International standards of testing should be done at source and we would not advocate for the export of gametes so countries can manage their own sperm and egg banks, legal requirements for testing and to limit issue for donor conceive people seeking their genetic families without necessary travel abroad to find the source of their DNA.	
136	Viville Stéphane		3	107	It should be precised that it concerns autosomic recevisse pathologies	Thank you. This was adapted as suggested.

137	European Society of Human Genetics (ESHG)	Genetic aspects and Legal aspects		<p>We do have serious concerns about the Genetic aspects section. Even if in the future there will be increased offer for genetic tests and increased openness in families about gamete donation, the risks of consanguinity and/or propagation of genetic diseases will never be fully avoided - considering also that this increased risk is introduced by normative actions, not by cultural habits. It is worrisome that a thorough discussion on these risk, including adequate references of analyses, has been overlook, and the resulting suggestion would be to completely discard these aspects. Limits currently sets at national level are largely based on these risks.</p> <p>One suggestion is made that comprehensive genetic testing will be mandatory on donors via the SoHO Regulation, which will be implemented in 2027. However, we feel that this is a misinterpretation of the legislation, which would lead to a potentially misleading conclusion and recommendation.</p> <p>In particular from the text of SoHO: <i>[Copy/paste of recital 28]</i> (does not mandate genetic testing, refers to other laws for those obligations) <i>[Copy/paste of recital 56]</i> (donor anonymity might be a mandatory requirement in some States and it will be enforced by SoHO as well in these cases. States might change their legislation in the future and become again more restrictive) <i>[Copy/paste of recital 62]</i> (excludes all private donations from genetic testing) <i>[Copy/paste of article 3(21)]</i> (mandates a donor registry) <i>[Copy paste of articles 58(1) and 58(3(b))]</i> (refers to individual Member States to set framework for donors' genetic testing, does not introduce any obligation)</p>	<p>Thank you for highlighting that the representation of the SoHO Regulation's requirement for genetic testing of donors was imprecise. Indeed, the Regulation only mandates genetic testing to the extent that national legislation allows for such testing, i.e., Member States still have a possibility to set their own rules/prohibit certain forms of testing. If no such national rules are set, the SoHO Regulation does set a standard requiring that such testing is performed on donors. This has been clarified in the paper.</p> <p>Donor anonymity is considered outside of the scope of this paper. Indeed, the SoHO Regulation only applies to donations in SoHO entities. This has been clarified in the paper. The fact that the SoHO Regulation includes a definition for "SoHO donor registration" does not mean that a donor registry is mandatory. Centralised donor registries at EU or national level are not mandatory under the SoHO Regulation.</p> <p>Lastly, the working group agrees that the placement of the statement that the propagation of genetic diseases should not be considered a relevant factor right after the details on screening requirements was misleading, since this statement did not relate to the protective effects of screening, but was supposed to act as an overall conclusion of the section, which was mainly based on the argument that a</p>
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					<p>The claim that donor-conceived individuals have “often lower risk” because of screening ignores:</p> <ul style="list-style-type: none">- Variable screening panels across clinics and countries.- Residual risk even after expanded carrier screening.- Conditions with incomplete penetrance, late onset, or poor detectability.- The possibility of false negatives or novel variants. <p>Thus the argument overstates the protective effect of screening.</p>	<p>higher number of donor siblings neither increases the genetic risks at an individual level nor the overall prevalence of genetic conditions. Therefore, this statement was removed from the end of the section.</p>
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138	Board of Health and Welfare (Sweden)		3	104	<p>Our interpretation of article 58.3 is that genetic testing is up to national legislation. Also, the risk is small, but as the recent case with the Danish donor demonstrates, testing cannot guarantee that a genetic disorder cannot be transmitted since all serious genetic disorders cannot be detected by testing</p>	<p>Thank you for highlighting that the representation of the SoHO Regulation's requirement for genetic testing of donors was imprecise. Indeed, the Regulation only mandates genetic testing to the extent that national legislation allows for such testing, i.e., Member States still have a possibility to set their own rules/prohibit certain forms of testing. If no such such national rules are set, the SoHO Regulation does set a standard requiring that such testing is performed on donors. This has been clarified in the paper.</p> <p>It is not the intention of the paper to state that genetic screening requirements fully mitigate the genetic risks for donor-conceived people. The placement of the statement that the propagation of genetic diseases should not be considered a relevant factor right after the details on screening requirements was misleading, since this statement did not relate to the protective effects of screening, but was supposed to act as an overall conclusion of the section, which was mainly based on the argument that a higher number of donor siblings neither increases the genetic risks at an individual level nor the overall prevalence of genetic conditions. Therefore, this statement was removed from the end of the section.</p>
139	Donor Conceived UK		3	98-107	<p>Misses the fact that the lack of donor limits can result in high numbers of people who are genetically related</p>	<p>Thank you. The working group agrees that there might be some added complexities in this case, but does not</p>

					siblings and make tracing and support far more complex	consider this aspect crucial for setting an international offspring limit.
140	Donor Conceived UK		3	98-107	<p>Donor Conceived UK does not agree that the propagation of genetic diseases is irrelevant when determining donor offspring limits. This position overlooks both scientific uncertainty and the lived realities of Donor Conceived People (DCP).</p> <p>No genetic screening regime can eliminate risk entirely. Not all genetic conditions are known, routinely screened for, or fully understood at the time of donation, and some conditions only become apparent later in life or across multiple genetically related individuals. As the number of offspring created from a single donor increases, so too does the potential scale of harm should a heritable condition emerge. Sperm from donor with cancer-causing gene was used to conceive almost 200 donor conceived children - BBC News.</p> <p>Moreover, donor offspring limits are not solely a technical or statistical tool; they are a safeguard designed to limit the impact of systemic failures, incomplete screening, evolving genetic knowledge, and cross-border gamete use. Large sibling groups magnify the consequences of any oversight, error, or gap in regulation.</p> <p>From the perspective of DCP, the issue is not abstract. The repeated emergence of shared medical conditions across donor sibling networks demonstrates that genetic risk is experienced cumulatively, not hypothetically. Dismissing propagation of genetic disease as irrelevant minimises these risks and the burden placed on Donor Conceived People (DCP) to identify, manage, and communicate serious health information across expanding genetic networks.</p>	Thank you. It is not the intention of the paper to state that genetic risks for donor-conceived people are completely eliminated by genetic screening. The argument provided is that genetic risks are not related to offspring numbers.

					For these reasons, Donor Conceived UK maintains that the potential propagation of genetic disease must remain a relevant and proportionate consideration when setting donor offspring limits, alongside consanguinity, record-keeping, disclosure practices, and the long-term welfare of Donor Conceived People (DCP).	
141	Melinda Ildiko Mitranovici		3	104-105	testing donors for potentially life-threatening, disabling or incapacitating genetic conditions should be mandatory, however, even the history of predisposing factors would be helpful, until mandatory testing	Thank you. This aspect was added to the paper.
142	ASEBIR (Spanish Society of Reproductive Biology)	Genetic aspects			We wonder if it should be considered as a factor not only the overall prevalence of a genetic condition in the population, but the effect of limiting the number to limit an untested mutation once it appears to affect too many families.	Thank you. The arguments of the paper that offspring numbers are neither related to the individual risk of a genetic condition nor to the overall prevalence in the population also hold in case of untested mutations. Once it is detected that a serious condition was passed on by a donor, gametes from that donor are no longer used.
143	Annemieke Hoek	Genetic aspects Propagation of genetic disease			Line 108 : we do not agree with this statement of the ESHRE ;”propagation of genetic disease should not be considered a relevant factor when determining donor offspring limits”. While the chance of a carriership of a serious genetic disease is low in an individual donor, due to the large number of offspring the clinical impact in the offspring and their families is large (due to the large number of children/ families that will be involved). This should be taken into account limiting the number of offspring (see recent Li-Fraumeni syndrome in a donor and the risk for more than 196 children). The ESHRE should address this issue (low risk, but high impact) in the position statement.	Thank you. This statement was removed because its position right after the details on screening requirements was misleading. However, the argument in the paper is that a higher number of donor siblings is neither associated with the genetic risks at an individual level nor with the overall prevalence of genetic conditions.

144	Stichting Donorkind	Genetic aspects Propagation of genetic disease			<p>Line 108 : we do not agree with this statement of the ESHRE ;”propagation of genetic disease should not be considered a relevant factor when determining donor offspring limits”.</p> <p>While the chance of a carriership of a serious genetic disease is low in an individual donor, due to the large number of offspring the clinical impact in the offspring and their families is large (due to the large number of children/ families that will be involved).</p> <p>Furthermore we think that the risks should be calculated and binding guidelines should be set by professional organizations of clinical geneticists.</p>	<p>Thank you. This statement was removed because its position right after the details on screening requirements was misleading. However, the argument in the paper is that a higher number of donor siblings is neither associated with the genetic risks at an individual level nor with the overall prevalence of genetic conditions. Please reach out to professional organisations of clinical geneticists directly for any requests to them.</p>
145	CECOS (Centre d’Etude et de Conservation des Oeufs et du Sperme) Federation	The genetic risks			<p>It is true that they are, in principle, less significant for people born from donation than for others, as donor candidates are genetically screened. However, genetic testing varies from one country to another country, and the SoHO regulation applicable in 2027 also leave some leeway regarding mandatory genetic testing. Furthermore, despite genetic tests, abnormal dissemination of genetic susceptibility is still possible, especially since the limit on the number of offspring is high. If we consider the group of donor siblings, the consequences in the event of an unidentifiable risk would be very damaging. Therefore, it should not be written that “the propagation of genetic diseases should not be considered a relevant factor when determining donor offspring limits,” but rather “although many donors undergo genetic screening, the risk of spreading a rare susceptibility persists even if the probability is low, so a limit must be set.”</p>	<p>Thank you. This statement was removed because its position right after the details on screening requirements was misleading. It is not the intention of the paper to state that genetic risks for donor-conceived people are completely eliminated by genetic screening, only that the risk is not related to offspring numbers.</p>
146	Department of Clinical genetics, Rigshospitalet, Copenhagen	Genetic aspects			<p>Lines 104-109: “testing donors 104 for potentially life-threatening, disabling or incapacitating genetic conditions with a significant 105 prevalence in the donor population will become mandatory as of 2027 under the Substances of Human 106 Origin (SoHO) Regulation. Therefore, the propagation of genetic diseases should not be considered a relevant factor when determining donor offspring limits”. This does not</p>	<p>Thank you. The statement that propagation of genetic diseases should not be considered a relevant factor was removed because its position right after the details on screening requirements was misleading. It is not the intention of the paper to state that genetic risks for donor-conceived people are</p>

					take into account the possibility of mosaicism in the donor. Suggest adding: "However, as gonadal mosaicism can never be ruled out, and the serious implications of these genetic diseases has been shown multiple times, this is a relevant factor when determining donor offspring limits"	completely eliminated by genetic screening, only that the risk is not related to offspring numbers.
147	JUAN JOSÉ GUILLÉN			107	The argument overlooks the unavoidable residual risk in genetic testing. A zero-risk scenario is unattainable due to de novo mutations, technical limitations, and germline mosaicism, all of which can bypass even the most stringent screening protocols. Consequently, offspring limits are a vital containment measure; they do not change individual probability, but they do prevent the creation of large-scale clinical clusters when a hidden pathology goes undetected	Thank you. The statement that propagation of genetic diseases should not be considered a relevant factor was removed because its position right after the details on screening requirements was misleading. It is not the intention of the paper to state that genetic risks for donor-conceived people are completely eliminated by genetic screening, only that the risk is not related to offspring numbers.
148	Michael Scholtes		3	107	This is not right, de novo mutations in a germ line are presently addressed in the press. We just cannot prevent this by testing, but just by enforcing compulsory follow-up and limiting the number of offspring to contain this problem.	Thank you. The statement that propagation of genetic diseases should not be considered a relevant factor was removed because its position right after the details on screening requirements was misleading. It is not the intention of the paper to state that genetic risks for donor-conceived people are completely eliminated by genetic screening, only that the risk is not related to offspring numbers.
149	Mary Wingfield		3	107-108	I feel this sentence is too strong because, while screening can eliminate specific conditions, it cannot avoid sporadic de-novo genetic variations, such as one recently described in the EU media. I would replace this sentence with something like the conclusion for the previous paragraph ie "Therefore, the propagation of genetic diseases is no longer such a pressing concern."	Thank you. The statement that propagation of genetic diseases should not be considered a relevant factor was removed because its position right after the details on screening requirements was misleading. It is not the intention of the paper to state that genetic risks for donor-conceived people are completely eliminated by genetic

						screening, only that the risk is not related to offspring numbers.
150	Marilyn Crawshaw		3	98-108	Although I agree with much of what you say in here, I think it misses the fact that the lack of donor limits can result in high numbers of people who are genetically related siblings and make tracing and support far more complex. This is different to genetic transmission to non-DC offspring and I suggest it needs acknowledging	Thank you. The working group agrees that there might be some added complexities in this case, but does not consider this aspect crucial for setting an international offspring limit.
151	Cryos International Sperm & Egg bank		3	107-108	We agree with this statement that the risk of passing on genetic diseases is not relevant in this context.	Thank you.
152	CRYOGONIA CRYOPRESERVATION BANK		3	101	This is also very true. As per the comment above, the general health of offspring created by donation does not demonstrate a prevalent risk for genetic disease, compared to the natural population.	Thank you.
Preferences of affected groups						
153	Michael Scholtes		3	110	The ESHRE should initiate a Ph.D. program to elucidate the standpoints of donors and recipients after proper information about the consequences of the donation process. This implies an informed consent to be established, identical for all countries.	Thank you. As this is not a comment on the contents of the paper as such, it will not be addressed further here.
154	Melinda Ildiko Mitranovici		3	120	donor offspring limits should be standardized	Thank you for sharing your position.
155	Astrid Indekeu		3	110-119	In case this might be helpful (as research results are scarce): regarding donors (Dutch [BADOK-study] and Belgian research data [KULeuven], not (yet)peer-review published showed that donors -even those with contact with DCP- had little understanding of the long-term implications of multiple donations (e.g. meeting multiple DCP). Even those who had met DCP of their donation. The focus was/remains on the need of intending parents not DCP. (due to lack of counseling?) Some expressed a limit that was set by 'a number that you can put a name to a face/ so know the person' Belgian (intending) parents in a current anonymous system had little perspectives on the possible meaning/impact of multiple donor siblings. (very little counseling on this topic)	Thank you for sharing these interesting insights. For reasons of transparency, we only cite resources that are publicly available in the position paper. Please feel free to share any publications on this research with us when they are ready.

					<p>Both results above show the importance of education campaigns.</p> <p>DCP had a huge variety (as said in the document 'results are inconsistent') with more people preferring a number of people you can have contact/some kind of relation with.</p> <p>This is in line with the challenge that DCP express when confronted with 'too many people to manage' and 'not knowing how many there are'.</p>	
156	Marilyn Crawshaw		3	110-119	<p>These comparisons are interesting insofar as the Danish study of sperm donors appears so far out of kilter with the others but I would suggest the inclusion of a sentence or two about the size of the studies, their methodology and any limitations. For example were all the donors several years on from completing donating; had any had contact with their DCP; how many had received counselling etc.</p>	<p>Thank you. Details on the study samples and methodology were added to the paper.</p>
157	Anonymous	Preferences of affected groups.			<p>Reference is made to a study by Cryos from 2014. A more recent survey among donors from the same sperm bank shows that many sperm donors believe that high numbers of donor offspring are acceptable. See Pennings et al. (2021) RBM 43: 700-707. 'Donors were also asked how many children they thought could acceptably be created with their sperm worldwide. We recorded the answers in five categories: (i) ≤ 10 (18.8%); (ii) between 11 and 99 (15.8%); (iii) ≥ 100 to unlimited (48.5%); (iv) limits per country (5.5%); and (v) 'don't know' (11.1%). No significant difference was found between ID-release and non-ID-release donors for this item.'</p>	<p>Thank you. The reference to the Cryos study from 2014 was replaced with this reference and the paper was updated accordingly.</p>

158	Paths to Parenthood		3	119	<p>Preferred limits – in our recent survey*, recipient parents/intended parents were asked their thoughts of international donor family limits and what these limits should be. Of the 612 respondents who answered this question,</p> <p>341 (56%) stated donors should be limited to 1-5 families 142 (23%) stated donors should be limited to 6 – 10 families 26 (4%) stated donors should be limited to 11-20 families 21 (3%) stated donors should be allowed to donate to 20+ families 9 (1%) stated donors should not be limited to a certain number of families 73 (12%) stated they were unsure</p> <p>Our survey findings show that recipient parents believe family limits should be vastly lower than what ESHRE are initially proposing (50 families). Whilst we appreciate that the figure of 50 is an initial aim, we feel this should be reduced far sooner than the 3 years as suggested in this paper.</p>	<p>Thank you for sharing these interesting insights. For reasons of transparency, we only cite resources that are publicly available in the position paper. Please feel free to share any publications on this research with us when they are ready.</p>
159	Cryos International Sperm & Egg bank		3	111-113	<p>Our more recent study of the same population of active sperm-bank donors (Lassen et al. 2024) supports these findings. Among 173 donors, 74% stated that the number of offspring did not matter. When asked what they considered an acceptable number, responses ranged from 3 to 100,000, with a median of 100 children.</p>	<p>Thank you for sharing these interesting insights. For reasons of transparency, we only cite resources that are publicly available in the position paper. We could not find the results described in this comment in the research letter published on this survey, so these findings were not included.</p>
160	Cryos International Sperm & Egg bank		3	115	<p>In our study of 39 US egg donors at Cryos International (Lassen et al. 2025 Egg donors' attitudes toward identifiability, offspring information, and genetic testing: DOI link), donors were asked how many children born from their eggs they considered acceptable. Responses were: 1–2 children (10.2%), 3-</p>	<p>Thank you. This information and the reference were added to the paper.</p>

					10 children (31%), more than 10 children (33.3%), and 26% did not know.	
161	Annemieke Hoek	Preferences of affected groups Organizations of donor conceived individuals			<p>Line 120. “The ESHRE contacted stakeholders for their views on donor offspring limit and perceived responses from 11 organizations; donor conceived people, donors, patients and gamete banks”. It is not transparent what the results of this survey actually was. The ESHRE should add the results as addendum to the position statement.</p> <p>In order to come to a definitive maximum of families coupled to a donor; we urge the ESHRE in near future to perform a larger survey with regard to the organizations representing donor conceived individuals, since their views should be the “heart and mind” of the ESHRE statement (line 155). Organizations of donor conceived organization should be sent an official survey by the ESHRE with questions regarding the maximum number of families created by a donor, the duration of distribution of the gametes, the spread across European countries etc. The results of such a survey should be published and analyzed so that we as ESHRE members, donors, donor conceived persons and recipient parents, are well informed about the wishes of the donor conceived organizations across Europe. Moreover, such survey should be leading in the final limits with respect to number of families and duration of distribution of gametes over time. The position statement of the ESHRE should be changed/ amended accordingly.</p>	Thank you. The information on this informal consultation of stakeholders was replaced by a summary of the responses received in the formal stakeholder review. The proposal for a survey among DCP organisations will be discussed internally at ESHRE.
162	Stichting Donorkind	Preferences of affected groups Organizations of donor conceived individuals			<p>In order to come to a definitive maximum of families coupled to a donor; the views of organizations representing donor conceived individuals should be leading. Organizations of donor conceived organization should be sent an official survey by the ESHRE with questions regarding the maximum number of families created by a donor, the duration of distribution of the gametes, the spread across European countries etc. The results of</p>	Thank you. This proposal will be discussed internally at ESHRE.

					such an survey should be published position statement of the ESHRE should be changed/ amended accordingly. Any guideline without transparency and consequences is an empty shell, marketing.	
163	Annemieke Hoek	Preference of affected groups Gamete banks Financial drivers in donor conception			Line 124: “gamete banks indicate international limits ranging from 60 families to no limits”. Here it should be added that gamete banks have large financial interest, e.q. private equity organizations invest in gamete banks, so these banks have to make profit for their shareholders. This is one of the drivers in the large number of recipients that are coupled to a donor. Moreover, also doctors and clinics have financial interests, part of the clinics are owned by private equity organizations, more treatments with donor gametes lead to more profit for doctors and clinics and private equity investors/ shareholders. The ESHRE should be open about the financial drivers in these donor gamete treatments. We owe that to the donors, the recipients and the donor conceived persons. This should be stated in the position paper.	Thank you. A mention of the financial interests of gamete banks was added to the paper.
164	Stichting Donorkind	Preference of affected groups Gamete banks Financial drivers in donor conception			Gamete banks have large financial interest, also doctors and clinics have financial interests, part of the clinics are owned by private equity organizations, more treatments with donor gametes lead to more profit for doctors and clinics and private equity investors/ shareholders. The ESHRE should be open about the financial drivers in these donor gamete treatments. You owe that to the donors, the recipients and the donor conceived persons. This should be stated in the position paper.	Thank you. A mention of the financial interests of gamete banks was added to the paper.
165	Donor Conceived UK		3	123-125	Re: “preferred family limits as expressed by gamete banks V DCP”: It is extremely important to acknowledge the inherent commercial incentives at play. Gamete banks benefit financially from maximising the number of offspring created from a single donor and therefore may have a vested interest in opposing stricter donor offspring limits. However,	Thank you. A mention of the financial interests of gamete banks was added to the paper.

					these commercial considerations must not be allowed to outweigh the long-term welfare, rights, and lived experiences of Donor Conceived People (DCP), who bear the consequences of large donor sibling networks throughout their lives.	
166	Donor Conceived UK		3	126-128	It is unsurprising that two organisations representing DCP have expressed opposition to the cross-border exchange of gametes, as DCP are those who must live with and manage the long-term consequences of such practices. The UK government, regulator and fertility industries focus has remained squarely on their duty of care in relation to the period surrounding treatments and donor recruitment and have largely avoided accepting any duty of care for the psycho-social fallout from the lifespan implications of creating life in this way. Donor Conceived UK urge for the rights and needs of DCP to be centred in fertility regulation and law. It is the only way to ensure ethical practice.	Thank you for sharing your views.
167	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		3	120-129	Consultations with gamete banks would understandably result in a positive forward surge for the market to expand and for their profits to increase. We strongly disagree with the idea that “While two organisations of donor-conceived people stated that they oppose the exchange of gametes between countries, one parent organisation has advocated for the need to support access to gametes from other countries to ensure access to treatments for patients from countries with low donor numbers” as it is not the role of one country’s citizens to provide gametes for another country’s recipients. This concept is based on cross-border gamete trading, further complicating the sourcing of genetic families for donor conceived people. We also perceive issues around ethics and exploitation, from cross-border gamete ‘donation’. We observe that the 11 organisations that ESHRE consulted with are not named in the footnotes.	Thank you. A mention of the financial interests of gamete banks was added to the paper. The information on this informal consultation of stakeholders was replaced by a summary of the responses received in the formal stakeholder review.
Practical aspects on compliance and enforcement						

168	European Society of Human Genetics (ESHG)	Practical aspects on compliance and enforcement			<p>This is one of the key elements, however, it would seem not fully elaborated. Are there any existing registries within countries that can be used as model, and potentially be linked up via adequate data sharing models?</p> <p>The text implies GDPR makes an international registry extremely difficult to create. However GDPR permits processing of sensitive data for public health, quality and safety of care, and regulatory oversight, provided safeguards exist. Many EU-wide health registries already exist (e.g., rare disease registries, organ donation systems).</p>	Thank you. We consider that building an international registry is a challenging and time-consuming task for a variety of reasons, so the mention of the GDPR was removed to avoid the impression that this is the sole source of complications.
169	Cryos International Sperm & Egg bank		4	130-43	<p>We agree that compliance with the GDPR requirements will make the establishment of a centralized international donor registry a complex and time-consuming task. We support the introduction of mandatory reporting of live births resulting from donor gamete treatments.</p> <p>This would provide a more accurate basis for monitoring offspring limits and improve transparency. Currently, Danish legislation only requires reporting of a confirmed viable pregnancy, not live births, which illustrates the need for harmonized standards across jurisdictions.</p>	Thank you.
170	Lisa Ransome	Practical aspects on compliance and enforcement			<p>It is understood there are limitations to the ability to confirm and implement and regulate cross and inter gamete bank donations from the same individual, without significant changes in legislation, and registration systems. However, there are still ways in which this can be regulated and monitored in more successful ways than it currently is.</p> <p>Given the majority of individuals undertaking donor treatment will do so through a registered fertility clinic (irrespective of country), and there are an increasing number of countries who either have donor registers (UK, NZ, Australia, The Netherlands) or use tracking of donor (Spain), there is capacity for the donor banks to be tracking the number of families created from a</p>	Thank you. The recommendation that gamete banks should monitor adherence to international limits within their own distribution is already in the paper. The additional recommendation for an international donor registry aims to ensure appropriate monitoring in case a donor donates at multiple banks.

					<p>single donor.</p> <p>Families should be noted in the donor banks systems, not based on live births but rather by allocation of the donated gametes. It would ONLY be in the event of the recipient clinic confirming a family has had NO children AND ceased treatment, that this gametes allocation can then be reallocated.</p>	
171	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		4	141-143	<p>We cautiously support considerations of how families are counted and to ensure that clinics follow up with parents and report back on treatment outcomes to gamete banks. However, we suggest this is completed as an exercise resulting in proposed solutions, which we had hoped to see in the paper.</p>	Thank you.
172	Paths to Parenthub		4	130 - 143	<p>Here at <i>Paths to Parenthub</i> we would fully support a centralised international registry to record, store and cross check donor information. Many of our members who we support comment that they are concerned that a donor that they have selected may have donated to multiple other gamete banks internationally. A central registry would go some way to mitigate these concerns for parents and families.</p>	Thank you.
173	Astrid Indekeu		4	142	<p>To ensure clinics follow up: maybe add and to ensure parents report a birth (the Hart-act in NZ include explicitly responsibilities of parents as well)</p>	Thank you. The working group decided not to recommend imposing legal obligations on parents.
174	JUAN JOSÉ GUILLÉN			143	<p>A centralized European registry is essential and already mandated by the SoHO Regulation (2027) to ensure cross-border traceability. Although clinics currently implement follow-up protocols, the primary challenge remains patient loss to follow-up. It is vital to emphasize the moral obligation of patients to report outcomes to ensure the system's integrity.</p> <p>Furthermore, private donations must be prohibited to prevent individuals from bypassing clinical oversight and undermining the safety and limits established by official institutions.</p>	Thank you. Under the SoHO Regulation, aggregated activity data reporting will be mandatory (e.g., on how many donors, straws, total number of offspring from donation in a given year). A centralised EU-wide registry that allows monitoring offspring numbers per individual donor is currently not mandatory. The paper already emphasises the need to ensure proper follow up on treatment outcomes and highlights the risks of private donations.

175	Leah Gilman	Recommendations		<p>An overarching comment is that further consideration should be given to the fact that some clinic sperm donors will also donate informally (or privately, in the terms of the draft paper). Evidence for this is given in the table below.</p> <p>In light of this, I would suggest some additional recommendations:</p> <ul style="list-style-type: none"> - Education and publicity regarding the reasons for limiting offspring per donor are perhaps as important as the limit itself, particularly what we know about the impact large sibling groups have for donor conceived people. This information should be shared with (potential) donors and those considering donor conception. This will encourage donors to take responsibility for limiting their own donations (especially if they do go on to donate informally) and intended parents (who may move on to informal donor conception after attending a clinic) to seek out donors with lower numbers of people conceived from their donation. - All potential donors should be asked whether they have donated informally. If they say yes (and are still accepted as a clinic donor) then children born from previous donations should be taken into account in calculating limits. - This may be beyond the scope of this position paper but, given the research which demonstrates the negative impact of uncertainty about donor sibling numbers for donor conceived people, consideration should be given as to whether a voluntary register of informal donor conceptions should be created, which could be linked to national formal registries. This would enable more donor conceived people to be able to accurately count and potentially contact all their donor siblings. - Fertility clinics and sperm banks should make clear 	<p>Thank you for these recommendations. Counselling and information, as well as voluntary registers for informal donations, are considered outside of the scope of this paper. A recommendation that donors should sign a written declaration disclosing all previous donations and that these should be included in the family count is in the paper.</p>
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					<p>that their family limits are not a guarantee of how many people a donor has donated to and only apply to clinic donations.</p> <p>Full references for citations below: Gilman, L. (2017). Qualifying kinship: How do UK gamete donors negotiate identity-release donation? PhD Thesis. University of Edinburgh. Available at: https://era.ed.ac.uk/handle/1842/25467 (accessed 12.12.2025.) Graham, S., Freeman, T., & Jadv, V. (2019). A comparison of the characteristics, motivations, preferences and expectations of men donating sperm online or through a sperm bank. <i>Human Reproduction</i>, 34(11), 2208–2218. https://doi.org/10.1093/humrep/dez173 Nordqvist, P., & Gilman, L. (2022). <i>Donors: Curious Connections in Donor Conception</i>. Emerald Group Publishing.</p>	
176	Leah Gilman		4	130	<p>A highly significant practical consideration is the challenge of regulating donations per donor outside of licensed clinics and the recognition that an unknown number of clinic sperm donors will also donate informally (either before or after donating at a clinic).</p> <p>It is difficult to know what proportion of clinic sperm donors also donate informally but research shows that this does happen. Whilst not a statistically representative sample, in my ongoing qualitative research into UK informal donor conception, 9 out of 19 informal sperm donors who participated in interviews and a further 4 out of 11 who responded to a questionnaire reported that they had donated in a clinic as well as informally. Of course, this is unlikely to directly correspond with the proportions of clinic donors who also donate informally. Nevertheless, it suggests there is an overlap between these</p>	Thank you.

					<p>populations. This has also been documented in other survey-based and qualitative interview studies with UK sperm donors (Nordqvist and Gilman 2022, Graham et al. 2019).</p> <p>I do not think this is a reason not to impose a ‘family limit’ on clinic sperm donation. However, I suggest some recommendations (above) which could help to address this practical limitation and further the broader ethical aims of having an international limit in the first place.</p>	
Legal aspects						
177	Anonymous	Legal aspects			<p>How can an international limit protect offspring? No argument is offered. Or is this again only a reaction to those who want to make contact and is the protection of the interests of all others whose parents will have to go on the internet ignored? This needs additional arguments. Otherwise it assumes what needs to be proven, namely that such a rule protects the DCPs in general.</p>	<p>The arguments why donor offspring limits protect offspring, namely by mitigating feelings of uncertainty, distress and commodification, are provided in the section on psychosocial aspects.</p>
178	Annemieke Hoek	Legal aspects			<p>Line 148- 152; Indeed the ESHRE Should enforce steps to implement an additional standard for offspring protection, so that the number of families and hence offspring after donor conception is legally limited under the EU SOHO Regulation with a delegated act under article 58. Furthermore, the ESHRE should advocate to install inspection authorities, audit etc. for gamete banks, so that regulations are implemented and transparent.</p>	<p>If an offspring limit is added under the SoHO Regulation, the same inspection system as for other standards under the SoHO Regulation will apply.</p>
179	Stichting Donorkind	Legal aspects			<p>the ESHRE should advocate to install inspection authorities, audit etc. for gamete banks, so that regulations are implemented and transparent. Any guideline without enforcement is an empty shell.</p>	<p>If an offspring limit is added under the SoHO Regulation, the same inspection system as for other standards under the SoHO Regulation will apply.</p>
180	Lisa Ransome	Legal Aspects			<p>It is acknowledged the ability at present to implement true international limits for recipient families is limited, as noted this would take significant political efforts, and there would be limited capacity for enforcement. However, should an EU, and potentially an “export” out</p>	<p>If an offspring limit is added under the SoHO Regulation, the same inspection system as for other standards under the SoHO Regulation will apply. This system also includes provision to</p>

					of the EU be set, then laws should be set up for the capacity to complete auditing of donor banks for complying with these numbers, could still feasibly sit within the remit of EU authorities, and sanctions provided to banks who do not comply with these total limits.	ensure compliance with EU standards in the case of imports.
181	Fertility Exeter	International enforceability			May be impossible to monitor and enforce international limits outside of Europe with more established national data collection and regulatory systems.	Thank you.
182	Melinda Ildiko Mitranovici		4	147	In terms of legal aspects, I agree that an EU-wide limit could represent a feasible first step	Thank you.
ESHRE position and policy recommendations: Introductory text						
183	Annemieke Hoek	Preferences of affected groups Donor conceived individuals And recipient parents			<p>Line 155; ESHRE considers the wellbeing of donor-conceived people to have the highest priority determining the limits on the number of offspring/ families. If this is indeed the most important ethical position of the ESHRE, than the ESHRE should propose the limit for the number of families coupled with a donor in Europe, not to 50, but use the limit that the donor conceived organizations propose being a 10 maximum (see line 123).</p> <p>The US donor Conceived Counsel (USDCC) published in 2022 a survey; a broad support for limits on the number of families per donor in 483 respondents; 93% donor conceived individuals, 80% of recipient parents, and 54% of sperm donors supported the limit of the number of families to 10 per donor. Donor conceived individuals favored 7 families per donor and recipient parents 12 families per donor. Donors favored on average 17 families per donor. (U.S. Donor Conceived Council. 2022 Advocacy Survey Results - U.S. Donor Conceived Council. (Accessed 19th of March 2025). Available from: https://www.usdcc.org/2022/11/16/2022-advocacy-survey-results/)</p> <p>Ethical alignment with the statement in line 155 should automatically lead to reduction of coupling of donors</p>	Thank you. While ESHRE considers the wellbeing of donor-conceived people to be of highest priority, the position paper also states that other aspects such as considerations on access to treatment also need to be taken into account and balanced.

					to maximum of 10 families. If the ESHRE wants a stepwise reduction than we agree to set the maximum at 15, for the time being (see below).	
184	Stichting Donorkind	Preferences of affected groups Donor conceived individuals And recipient parents			Line 155; ESHRE considers the wellbeing of donor-conceived people to have the highest priority determining the limits on the number of offspring/ families. If this is indeed the most important ethical position of the ESHRE, than the ESHRE should propose the limit for the number of families coupled with a donor in Europe, not to 50, but use the limit that the donor conceived organizations propose being a 10 maximum (see line 123). The US donor Conceived Counsel (USDCC) published in 2022 a survey; a broad support for limits on the number of families per donor in 483 respondents; 93% donor conceived individuals, 80% of recipient parents, and 54% of sperm donors supported the limit of the number of families to 10 per donor. Donor conceived individuals favored 7 families per donor and recipient parents 12 families per donor. Donors favored on average 17 families per donor. (U.S. Donor Conceived Council. 2022 Advocacy Survey Results - U.S. Donor Conceived Council. (Accessed 19th of March 2025). Available from: https://www.usdcc.org/2022/11/16/2022-advocacy-survey-results/) Ethical alignment with the statement in line 155 should automatically lead to reduction of coupling of donors to maximum of 10 families.	Thank you. While ESHRE considers the wellbeing of donor-conceived people to be of highest priority, the position paper also states that other aspects such as considerations on access to treatment also need to be taken into account and balanced.
185	Donor Conceived UK		4	155-156	If ESHRE considers that the wellbeing of DCP should have the highest priority when determining limits on the number of offspring per gamete donor why is more weight not being put on consanguinity and inherited genetic disorders?	Thank you. The reasons why consanguinity and inherited genetic disorders are not given more weight are that the risk of consanguinity is very low, especially when considering international limits with a large geographical spread, and that the risk of inherited genetic disorders is not

						related to offspring numbers, as described in the section on genetic considerations. More weight on these aspects would have led to higher proposed limits, not lower ones.
186	CECOS (Centre d'Etude et de Conservation des Oeufs et du Sperme) Federation	The wellbeing of donor-conceived people			We also believe it is necessary to give priority to the wellbeing and opinions of donor-conceived people (and donors) over those of gamete banks. These are the people who will live with the story of their conception and who, depending on the country in which they live, will have certain rights such as access to their origins (allowing contact between donor and offspring) or even the possibility of meeting their donor siblings or the children of their donor. Assisted reproductive technology involving gamete donation must remain an activity in which medical rules take precedence over commercial rules. It is neither ethical nor medically acceptable for the international limits on the number of offspring to be determined by profitability arguments. We endorse the ESHRE position, which emphasises this priority.	Thank you.
187	Astrid Indekeu	LT versus ST			The document clearly states (P4L155) that DCP should have the highest priority. In this way it is phrased in terms of 'priority order of stakeholders'. It might be valuable to additionally explain that donor conception asks for a long-term (LT) perspective/approach (including the DC child growing up to DCP, understanding all the implications of DC) rather than a short-term approach (eg. With a focus on highest treatment availability and access)	Thank you. We consider that considerations on access to treatment also have a long-term relevance, since a lack of access can lead some people to remain involuntarily childless in the long term. Therefore, this distinction was not added.
188	Fertility Europe	Donor families as main stakeholders in consultation on limits			We strongly agree that the donor-conceived people have to be given a strong voice as those who had no say at the time of decision making about using donated gametes, but it is as important to include donors and patients especially as we know that the systems in place are not entirely free from coercion with lack of informed choices. Mutually agreed and accepted systems that weigh interests and long-term wellbeing	Thank you. The sentence was amended and a specific reference to the wellbeing of donors and patients was added.

					of all affected have a chance to provide a lasting change and it is important to link wellbeing of donor-conceived people and their families.	
189	Donor Conception Network		3	155-156	ESHRE Position and policy recommendations Are the first two lines (155-156) quite right without any additional reference to the needs and wishes of prospective parents, donors and clinics/banks? We agree, DCPs are and should be highest priority in one sense, but this document actually seems to be trying to balance all parties involved and we would support this balance	Thank you. The statement that the wellbeing of donor-conceived people should have the highest priority was kept, but it was clarified that there is also a need to take the wellbeing of donors and patients into account and aim for a balance.
190	CRYOGONIA CRYOPRESERVATION BANK		4	159	It is, however, notable that the donor-conceived people's parents consent on their behalf when they decide to embark in the donation process as a selected mode of conception.	Thank you. The working group does not consider it relevant to add this aspect, since consent from the parents does not mean that donor-conceived people themselves agree with the mode of conception.
ESHRE position and policy recommendations: Setting an international limit						
191	Donor Conceived UK	General			It would be good if there were to be a way of including the UK in any EU scheme.	Thank you for sharing this consideration.
192	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		4	145-152	EU-wide limits would not apply to the United Kingdom and we are unclear as to how, if this is to be a core principle or position for EHSRE going forward, how UK members would continue to participate in ESHRE, or if the UK govt would be approached to align UK law with an international approach.	Thank you for sharing your concerns. While the EU policies recommended in the paper will not apply to UK practice, this will in no way affect the participation of UK members in ESHRE.
193	Donor Conceived UK		4	167-168	In the absence of an international body with the authority to impose a global donor offspring limit, we support ESHRE in calling on the EU to introduce an EU-wide limit. However, given the scale of gamete imports from the United States into the EU, such a measure alone risks having only a limited practical impact.	Thank you. The position paper recommends that the requirement to comply with the proposed limits should also apply to banks outside the EU as a pre-requisite to be able to import gametes into the EU.
194	Michael Scholtes		4	164	The ESHRE should take the lead, calling on the EU will probably not even wake up the politicians. Furthermore, many in the European parliament are not well informed and afraid of speaking out. It is always	Thank you. Mandatory international limits can only be set in legislation, which is why this position paper makes a practical proposition for legislative change and calls on the EU.

					easier when a practical, well deliberated, proposition is brought in by experts.	
195	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		4 & 5	163-209	<p>On proposals:</p> <ol style="list-style-type: none"> 1. International limit beginning with the EU - the UK is no longer a EU member so this does not impact the UK regulatory body, HFEA or have any influence on UK laws. 2. Number of families - we recognise that genetically related children are best raised in families together and not across different family situations (location, culture, education, financial situation and religion) to avoid future conflict, negative outcomes and emotional disruption. We would like to see low family limits (similar to that of Austria, Bulgaria, Croatia, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Romania, Slovakia and Slovenia) 3. Donor setting limits - we cautiously support this proposal. 4. Cross border gamete 'exchange' - we reject this proposal. 5. Maximum international limit - of 15 families "or lower per gamete donor". ESHRE should begin at 15 and not 50 families and seek to reduce this to 3-5 families over a period of time. 6. Self-imposed limits from clinics - this will not be implemented by goodwill as profits will suffer and clinics are imposing limits of 50-60 families as is noted in the paper. 7. Generational timespan - a 20 year age gap would leave young adults with newborn donor siblings. A decade would keep siblings closer in age which improves likelihood of sustaining ongoing relationships in adulthood. 8. Public participation and education programmes, and donor recruitment strategies - We strongly reject this proposal and refer to the public recruitment and advertising programme rolled out by the Scottish 	Thank you for sharing your views. Your concerns regarding the market language were discussed with the working group and it was decided to keep the terms, since this is the established language in the SoHO Regulation. We have added an acknowledgement of the issues with these terms in the context of gamete donation and an explanation why it is used to the paragraph on use of language in the introduction.

					<p>Government that was taxpayer funded and yielded few donations.</p> <p>We observe the market language of ‘shortage’ and ‘supply’ which is the language of manufacturing or trade. We find it to be predatory, coercive and dehumanising. It is not a woman’s job to supply her eggs, nor is it a man’s job to supply his sperm in order for other people to become parents. This suggest a ‘softening up’ of the public to be more open and accepting of large genetic families which are disjointed and disassociated from the nuclear family, as a way to normalise and legitimise, through law reform, the proliferation of the fertility industry.</p>	
196	Leah Gilman		4	169	<p>May want to define ‘family’ here. Will it include use by one parent following separation and re-partnering?</p>	<p>Thank you. We have added a footnote to explain the working group's understanding of the term "family". An exact definition that provides legal certainty in all cases needs to be developed by regulators and set in legislation.</p>
197	Board of Health and Welfare (Sweden)		6	228	<p>How should "family" be defined in the context of pregnancy slots? Should a same-sex couple have one or two pregnancy slots? A definition of family is needed.</p>	<p>Thank you. We have added a footnote to explain the working group's understanding of the term "family". An exact definition that provides legal certainty in all cases needs to be developed by regulators and set in legislation.</p>
198	Human Fertilisation and Embryology Authority (HFEA)				<p>The recommendation outlined in the position paper to use a limit in terms of the number of families rather than the number of individuals born is consistent with the UK framework, which is also based on a family limit rather than a child limit.</p>	<p>Thank you for sharing this information on the UK context.</p>
199	The Danish Business Association for Egg and Sperm Donation (BFSD)	Families, not children			<p>BFSD fully supports ESHRE’s recommendation that any EU-wide limit should be set in terms of families rather than individual children. This approach protects reproductive autonomy, allows families to complete their family using the same donor if they wish, and</p>	<p>Thank you.</p>

					avoids unintended consequences such as stranded embryos or forced donor changes.	
200	Annemieke Hoek	Setting international limits Number of Families as opposed to number of children			Line 169-177; We agree with the ESHRE statement that any limit on the number of offspring per donor should be set in terms of the number of families, so that donor conceived children within a family are genetically linked.	Thank you.
201	Stichting Donorkind	Setting international limits Number of Families as opposed to number of children			We agree with the ESHRE statement that any limit on the number of offspring per donor should be set in terms of the number of families, so that donor conceived children within a family are genetically linked. Though we think that these genetic networks should be as locally as possible to give all children easy access to their biological family-members.	Thank you.
202	Laura Fernández Olmedilla	Families rather individuals (lines 169-170)			I agree the limit of donor offspring should be set in terms of the number of families rather than the number of individual children born as this approach better reflects social reality and reduces the risk of effective consanguinity. I believe that this same criterion should be applied in Spain where the donor's own children are taken into account in that maximum number of six, and they should count as one.	Thank you. Recommendations on the Spanish national situation are considered outside of the scope of this paper.
203	Aoife Campbell		4	169-177	I strongly agree with this point, any limit should be based on families, not individual children.	Thank you.
204	Paths to Parenthood		4	170	We would support limits of number of families as oppose to limits of the number of children, for similar reasons outlined in the proposal.	Thank you.
205	JUAN JOSÉ GUILLÉN			177	We strongly support the 'per family' limit, but the current text overlooks a crucial clinical argument. Evidence on the primipaternity hypothesis suggests that maintaining the same biological father for subsequent pregnancies reduces the risk of placental spectrum disorders caused by immunological maladaptation. Switching donors acts as a new 'primipaternity' event, re-introducing the risk of preeclampsia and intrauterine growth restriction (IUGR). Therefore, allowing families to complete their	Thank you. The working group decided not to add this aspect due to a lack of robust scientific evidence.

					reproductive plans with the same donor is not just a psychosocial preference, but a matter of maternal and fetal safety	
206	Board of Health and Welfare (Sweden)		4	169	Agree, it´s important to limit the number to families and not children	Thank you.
207	Donor Conceived UK		4-5	169-177	<p>Donor Conceived UK is concerned that this framing prioritises the preferences and reproductive agency of recipient parents over the long-term rights, welfare, and lived experiences of DCP.</p> <p>While we recognise the importance of allowing recipients to use cryopreserved embryos created as part of their treatment, the statement extends beyond this limited context to justify continued use of the same donor based on parental preference. Considerations such as strengthening sibling bonds, parental convenience, or minimising the number of donor connections are framed as decisive, yet the cumulative impact on DCP particularly the creation of large donor sibling networks is not addressed.</p> <p>The suggestion that shared donor genetics may strengthen sibling bonds reflects a parental assumption rather than evidence from DCP themselves. For many DCP, the primary challenge is not managing “too many donors,” but navigating an ever-expanding number of donor siblings, often across borders, with limited information, inconsistent records, and no legal obligation of disclosure.</p> <p>Moreover, the emphasis on reproductive agency for recipient families risks overlooking that DCP have no agency in these decisions, despite living with their consequences for life. When donor offspring limits are relaxed or bypassed to accommodate family preferences, the resulting increase in genetic connections disproportionately affects Donor Conceived People (DCP), not recipient parents or clinics.</p> <p>Donor Conceived UK therefore questions whether this approach genuinely places DCP at the centre of policy-</p>	<p>Thank you for sharing your concerns. Since this recommendation was supported by all other reviewers in the stakeholder review, including other DCP organisations, the working group decided to keep it.</p>

					making. Any framework that prioritises parental choice must be balanced against the rights of Donor Conceived People (DCP) to manageable genetic networks, protection from consanguinity risks, and a regulatory system that limits harm rather than redistributing it onto those with the least power in the process.	
208	Michael Scholtes		5	177	The number of frozen straws of germ cell donors that have been sold to clinics and sometimes patients, that have not been used, is not known. Neither the number off un-used frozen embryos. It should be forbidden to donate/sell these leftovers to other individuals/clinics	Thank you. The working group does not see a need to prohibit the donation of frozen embryos created with donor gametes, as long as adherence to the overall donor offspring limits is monitored and the limits are not surpassed.
209	Annemieke Hoek	Setting international limits for donors			Line 178; We agree that a donor should be able to set lower limits for the number of families then mandated by regulations	Thank you.
210	Stichting Donorkind	Setting international limits for donors			Line 178; We agree that a donor should be able to set lower limits for the number of families then mandated by regulations. This should be told to donors clearly and preferably. And this should be audited and enforced.	Thank you.
211	Aoife Campbell		5	178	Strongly agree	Thank you.
212	Leah Gilman		5	178	The option for donors to further limit the numbers of families should be discussed with a counsellor and include full consideration of the pros and cons of a lower limit. In the UK, donors are often motivated to donate because of donor shortages– as discussed by clinicians and in the media (Gilman 2017). They may therefore feel obligated to donate to as many people as possible.	Thank you. Information and counselling is considered outside of the scope of this paper.
213	Donor Conception Network		5	178-179	Setting an international limit Is it realistic and manageable for clinic operations to allow donors to add their own limits? Does this add another layer of complexity that may lead to confusion and error in the long run?	Thank you for sharing your concerns. The word "Preferably" was added to this recommendation to acknowledge that it may not always be feasible.

214	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies		5	178- 179	In the United States, the State of Colorado, specifically the Colorado Department of Public Health and Environment (CDPHE), has a similar requirement that donors are to be offered the possibility of setting a lower limit for the number of families that can be created with their own gametes. Donors are educated on their ability to limit the number of families and acknowledge this in their consent agreement. However, California Cryobank (CCB) and Donor Egg Bank (DEB) USA do not allow donors to continue with the program unless they agree to the 25-family limit due to challenges, including administrative burden. These types of regulatory burden may impact access and availability of donor gametes to intended families.	Thank you for sharing this information.
215	Laura Fernández Olmedilla		5	178-179	I believe that the consultation with donors should only concern their reproductive plans, as they are free to make whatever donations they wish. They rarely show interest in my experience of limiting the number of births or families; they are only really interested in knowing whether it has been useful.	Thank you for sharing this information.
216	JUAN JOSÉ GUILLÉN			178	We disagree with the recommendation allowing donors to unilaterally set lower limits than those mandated by law. The regulation of offspring numbers should remain the exclusive prerogative of public health authorities and standardized European protocols, rather than being subject to individual discretion. Allowing donors to impose ad-hoc limits introduces logistical unpredictability and inefficiency into the system, especially considering the high resources invested in donor screening. Limits should be defined solely by scientific, psychosocial, and administrative criteria set by competent institutions to ensure equity and the sustainability of the supply, avoiding arbitrary restrictions based on personal preference	Thank you for sharing your concerns. The working group considers the autonomy of donors to be of high value and considers that it outweighs the logistical concerns raised.
217	Donor Conception Network		5	178-179	Setting an international limit Should donors be given the option to veto having their gametes exported?	Thank you. This point was added to the paper.

218	Leah Gilman		5	178	In addition, for the reasons already outlined in the position paper, donors should be given a meaningful opportunity to opt out of their gametes being exported.	Thank you. This point was added to the paper.
219	The Danish Business Association for Egg and Sperm Donation (BFSD)	Cross-border exchange of gametes			BFSD agrees with ESHRE that restricting the cross-border exchange of gametes is neither desirable nor realistic within the EU. Free movement of people and services is a fundamental EU principle and plays an important role in ensuring access to fertility treatment. However, the consequences of cross-border treatment and gamete exchange must be addressed at a political and regulatory level, rather than left to the industry alone. National family limits can be exceeded when patients use their rights defined in EU law to seek treatment abroad (with due protection of their privacy) and return home without those treatments being counted under national limits. This structural limitation of national regulation is precisely why an EU-level solution is required.	Thank you.
220	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies	Exchange of Gametes between Countries			We are also in support of the exchange of gametes between countries to ensure access to treatment for patients from countries with less donor availability.	Thank you.
221	Donor Conception Network		5	181-182	Setting an international limit - Harmonised EU framework We are in agreement with harmonising an EU wide framework if possible	Thank you.
222	Cryos International Sperm & Egg bank		5	181-182	In line with ESHRE, we do not see a need for restrictions on cross-border gamete donation, neither within or outside the EU.	Thank you.
223	JUAN JOSÉ GUILLÉN	Prevention of Waste and Optimization of Resources			The document should explicitly address the inefficiency of rigid national limits that force the destruction of valid biological samples. A clear example is the situation in Spain, where reaching the national limit (6 births) often mandates the destruction or discarding of remaining cryopreserved samples, even if the donor is perfectly healthy. This is an	Thank you. The working group decided against including recommendations on the form and content of national limits in this paper, since the scope is on international limits.

					ethically unjustifiable waste of biological resources, especially given the global scarcity of gametes. ESHRE should recommend that national limits apply strictly to the resident population, while explicitly allowing the use of "surplus" samples for cross-border patients (non-residents) or export to other EU countries, provided the global EU limit (e.g., 50 families) is respected. The regulations should encourage the circulation of safe gametes to treat international patients rather than destroying them due to a purely local administrative cap that poses no consanguinity risk to the non resident population	
224	JUAN JOSÉ GUILLÉN			272	We strongly support the stance against restricting cross-border exchange. To make this effective, ESHRE should explicitly recommend that national limits regarding offspring numbers should only apply to residents of that country. Regulatory frameworks must clarify that once a national limit is reached (e.g., 6 births in Spain), the remaining cryopreserved samples should not be destroyed, but rather cleared for export to other EU countries where the donor has not reached the limit, provided the global EU cap (50 families) is respected. This distinction is vital to prevent the unethical waste of viable biological resources	Thank you. The working group decided against including recommendations on the form and content of national limits in this paper, since the scope is on international limits.
225	Annemieke Hoek	Setting international limits			Cross border exchange should be part of the survey that organizations of donor conceived individuals should answer in a survey that the ESHRE should perform (see above). For donor conceived individuals it is far more difficult to get contact with a donor in a foreign country, let alone differences in language in case one wants to contact donor or the half sibling network across Europe.	Thank you. The proposal for the survey will be discussed internally at ESHRE.
226	Stichting Donorkind	Setting international limits			Contact for donor conceived individuals it is far more difficult with a donor in a foreign country, let alone differences in language in case one wants to contact donor or the half sibling network across Europe. Cross border exchange should be as little as possible.	Thank you for sharing these concerns. Given today's possibilities of making international connections through the internet, the working group considers that a restriction of cross-border exchanges is not sufficiently justified

227	London Sperm Bank	Limits must be evidence-aware, enforceable, and economically sustainable			<p>We agree there is no “perfect” number today. However, we are not aware of a published empirical basis that can firmly justify an “ideal” target such as 10–15 families per donor at international scale. Low limits that are not commercially viable or enforceable risk creating unintended consequences: reduced regulated supply, increased dependency on imports, and/or diversion into unregulated private donation, where traceability and safeguards are lost. We encourage ESHRE to frame any “ultimate” target as provisional and evidence-seeking, explicitly conditioned on feasibility (including market dynamics and enforcement capacity) and real-world outcomes.</p>	<p>Thank you for sharing these concerns. Given that several smaller gamete banks operate with such low self-imposed limits, we do not agree with the claim that they are not commercially viable. Furthermore, the paper already recommends that the impacts of newly introduced limits on access to treatments should be continuously monitored and that further research should be conducted on the ultimate ideal limit.</p>
228	London Sperm Bank	A staged-release approach for newly approved donors			<p>We recommend ESHRE add a “staged release” concept: newly approved donors should be distributed to a limited initial number of families globally for a defined period (e.g., first 12–18 months), before broader release, so that if a serious concern emerges early, spread is limited. A practical illustration could be an initial tranche in the range of 10–30 families worldwide (to be defined by regulators/banks), with escalation only if no significant adverse signals arise.</p>	<p>Thank you. This recommendation was not included, since the propagation of genetic disease was not the guiding concern that led to the recommendation of an international limit in this paper. Moreover, a staged release model would increase age gaps between donor siblings, which brings its own challenges.</p>
229	Anonymous	Recommendations			<p>Why is the limit 50 and how is this an improvement from 75? Is lower better? Again, this needs an argument. Moreover, the one argument that is offered is strange to say the least: there are already a few international sperm banks that use this limit. First is this an argument? Second, it refers to the European Sperm Bank of which we know now that they did not respect their own limit anywhere.</p> <p>The same applies to 15: why this number? No argument is offered. Such a low limit will have major repercussions on access. Since we have to balance pros and cons, ESHRE needs strong arguments to put this forward. To use the document’s own type of argument, that same sperm bank charges 11.000€ for a family limit of 15 families. For an overview of the financial impact of limiting donor use, see Pennings, G.</p>	<p>Thank you. The term "improvement" was changed to "reduction". Furthermore, a more detailed explanation of the rationale behind the proposed approach was added to the paper.</p>

					(2025) The management of donor information, donor anonymity and family limits by international sperm banks. Ethics, Medicine and Public Health 33: 101153. ESHRE should think about the issue of access, otherwise it does what many other countries did: impose rules, think about the consequences for the patients later.	
230	Cryos International Sperm & Egg bank		5	191-200	To support the hypothesis of the position paper Cryos will establish a selection of donors with overall quotas of 50 and 15, and we will thereby gain experience with the demand for these. For both, the price will increase to cover administrative costs. The price of sperm at 15 will be approximately three times higher than at 50, so that the fixed costs of finding and managing donors are covered. We will therefore let market forces determine whether there is demand for the suggested limitation or not.	Thank you for sharing this information.
231	European Society of Human Genetics (ESHG)	ESHRE position			<p>We welcome ESHRE position in proposing an international limit on the number of offspring per donor, and we agree that a EU-wide limit would be sensible, in consideration of enabled cross-border healthcare.</p> <p>However, the proposal seems vague and not grounded in principles and science.</p> <p>An assessment (even a list) of the criteria used in each of the States which have defined a limit is missing.</p> <p>The 50-family limit suggested as temporary measure is not backed by any criteria, with the exception of the existing self-imposed limits of several gamete banks (unclear how many and which proportion). The goal of reaching a maximum international limit of 15 families or lower per gamete donor, again, is not supported by any clear criteria. The proposal suggests that this limit might not even been recommended as a 'transition period' of 3 years should take place, during which the limit might be further changed. It is unclear on who would be in charge to set up the timeline, the criteria for the review and ultimately the definition of the</p>	Thank you. A more detailed explanation of the rationale behind the proposed approach was added to the paper. The different considerations driving existing national limits which are also relevant to international limits are described in the first part of the paper.

				<p>maximum number of families created per donor. It is not clear what is the current working framework of gamete banks, as what would seem a suggestion for new self-regulations, such as limiting new donations where it is not yet known if a previous donation ended up in liveborn children or not, or keeping a clear register of donor and donations, would seem already in the scope of good practice and in some cases legislation. More clarity on current best practices and legislation should be provided.</p>	
232	Karla Turner	General		<p>I welcome ESHRE's work in seeking to harmonise guidance on donor gamete limits across jurisdictions, recognising the complex ethical, clinical and social issues involved.</p> <p>I support the principle that limits should prioritise the welfare of donor-conceived people while also enabling access to donor treatment in a sustainable and equitable way. A key challenge is achieving an appropriate balance. As already identified, limits that are set too low risk unintended consequences including donor shortages and an increase in purchase prices as demand outweighs supply.</p> <p>With regard to setting a limit, it does feel somewhat like plucking a number from thin air. What feels manageable to one person may not appeal to another. What is important, is that donors and recipients are appropriately counselled and that donor-conceived individuals have access to the right support.</p> <p>Although I recognise the urgency to set these limits, I feel that thought should be given to the 'bigger picture' to prevent the creation of further issues.</p> <p>Donor gametes already currently 'retail' for thousands of pounds. This not only forces some patients into seeking private, unregulated arrangements, it also</p>	<p>Thank you. A more detailed explanation of the rationale behind the proposed approach was added to the paper. Price regulations for gamete banks are considered outside of the scope of this paper.</p>

				<p>encourages people to seek invasive treatments such as IVF/ICSI instead of simple insemination techniques purely from a cost effectiveness point of view. Any reduction in family limits will undoubtedly lead to an increase in these prices as banks seek to reclaim lost income. Imposing a 'sensible' limit on these prices or published guidance which would highlight if a bank was above average may help to mitigate this risk and prevent excessive profiteering. As limits are already in place for donor compensation payments, it seems unbalanced that limits do not exist downstream.</p> <p>Patients in need of donor gametes are completely at the mercy of this commercialized world that has been created. A concurrent harmonisation of family limits, storage length and commercial regulation would undoubtedly have a positive impact on patient experience.</p>	
233	The Danish Business Association for Egg and Sperm Donation (BFSD)	On the proposed 50- family limit		<p>ESHRE recommends an initial EU-wide limit of 50 families, with a gradual reduction over time. BFSD notes that while several gamete banks (mainly local banks or banks connected to clinics supplying in-house fertility treatment) already operate with self-imposed limits in this range, most international banks apply higher limits, such as 75 families, or no limit at all. Applying higher limits helps ensure access to care for a larger number of patients, including more disadvantaged countries where access to health care is substantially more difficult than in Europe. Based on practical experience, BFSD concludes that even a 50-family EU-wide limit is likely to have significant consequences for donor availability, patient choice, fully loaded treatment costs for the patient and for society, and reduced access to treatment unless donor recruitment is actively and sustainably supported. Rather than viewing the number in isolation, BFSD therefore emphasises that any EU-wide limit must be harmonised, enforceable, and accompanied by a</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>

					<p>central registry and concrete measures to secure donor supply. Without oversight, numerical limits risk being either symbolic or disproportionately restrictive in practice.</p> <p>We also strongly encourage a uniform approach to national family limits, based on the same underlying algorithm (number of donor-conceived children per million citizens) and interpreted consistently across countries. This includes alignment on the treatment of foreign nationals, siblings, existing embryos as well as ensuring patients have the right to select their donor</p>	
234	London Sperm Bank	Positioning of the proposed 50-family EU-wide limit and the “15 families” aspiration			<p>We support ESHRE’s proposal for an EU-wide 50-family limit as a pragmatic and immediately implementable step. We recommend ESHRE be careful about how the “15 families or lower” figure is presented: in the absence of strong empirical justification and considering enforceability and commercial sustainability, 15 should be framed as a hypothesis/aspiration for research and evaluation, not as an implied end-state. In practice, 50 families may represent the only enforceable international ceiling in the near term, and potentially for longer than anticipated, unless evidence and system capability (registry coverage, compliance mechanisms, donor recruitment) support a lower threshold.</p>	<p>Thank you. The paper already recommends that the impacts of newly introduced limits on access to treatments should be continuously monitored and that further research should be conducted on the ultimate ideal limit.</p>
235	London Sperm Bank		5	183-197	<p>This section is excellent and clearly written. We suggest adjusting the framing of the “15 families or lower” point to avoid implying that 15 is a settled “ideal” number. Consider explicitly stating that:</p> <ol style="list-style-type: none"> 1. there is currently limited empirical basis for an “ideal” threshold; 2. feasibility/enforceability and access impacts must be weighed alongside psychosocial aims; and 3. the “15” figure should be treated as provisional and subject to revision based on monitoring, market response, and new evidence. <p>If ESHRE retains “15” as an aspiration, we recommend adding a sentence noting that 50 may remain the</p>	<p>Thank you. The paper already recommends that the impacts of newly introduced limits on access to treatments should be continuously monitored and that further research should be conducted on the ultimate ideal limit.</p>

					operative ceiling for longer unless system capability and supply economics allow a safe reduction.	
236	CRYOGONIA CRYOPRESERVATION BANK	European limits			The 50-family European donation quota is reasonable and should be supported. Any attempt to further limit the use of donated gametes, especially at a level of 15 families, would inevitably lead to the well acknowledged consequences of donor gamete shortages, increased costs and limited access of recipients to regulated assisted reproduction services.	Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.
237	JUAN JOSÉ GUILLÉN			191	While we accept the immediate implementation of an EU-wide limit of 50 families to harmonize practices, we strongly advise against setting a predetermined goal of reducing this limit to 15 families. Such a restrictive target contradicts existing scientific consensus at the national level. For instance, the Spanish Fertility Society (SEF, 2018) determined—based on demographic reality and treatment efficacy—that a limit of 20 families or 25 newborns is safe within a single country (Spain). If a limit of 25 is mathematically safe regarding consanguinity within a population of 47 million, imposing a limit of 15 across the entire European Union (450 million) is scientifically disproportionate. The risk of accidental consanguinity decreases as the geographical range expands. Therefore, lowering the limit to 15 would restrict access to treatment based on psychosocial precaution rather than biological risk, ignoring the demographic evidence that supports higher limits as safe. We propose maintaining the focus on the 50-family limit and only considering reductions if future monitoring reveals specific psychosocial harms, rather than committing to an arbitrary figure of 15 that ignores national expert assessments	Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.

238	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies		5	191- 197	<p>The position paper states ESHRE ultimately supports a maximum international limit of 15 families or fewer per gamete donor. We are in support of a family unit limit of greater than 25 and urge ESHRE to consider a family unit limit greater than 25 as this allows for more access to treatment versus a 15-family unit limit. Smaller family unit limits will lead to reduced gamete accessibility, increasing challenges to patients including cost as they need to utilize donor gametes for family building.</p> <p>Furthermore, the American Society for Reproductive Medicine (ASRM) has recommended a limit of 25 pregnancies per donor within a population of 800,000 since 1998, based on a 1995 study by DeBoer et al. This guideline remains in place today. While ASRM's recommendation refers to pregnancies rather than family units, it is reasonable for fertility clinics and sperm banks that cap distribution at 25 family units worldwide to align with ASRM.</p>	Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.
239	Association of Reproductive and Clinical Scientists (UK)	Tapering limit			The introduction of a larger limit (~50 families) that tapers down is practical and workable, although we believe that a minimum timeline for the review of the figure should be included to ensure that it goes ahead.	Thank you. It was decided not to recommend a specific timeline, so that review of the figure would follow the general review process of EU legislation.
240	Melinda Ildiko Mitranovici		5	184	A 50 family limit is feasible	Thank you.
241	CECOS (Centre d'Etude et de Conservation des Oeufs et du Sperme) Federation	The proposition			The initial limit proposition of 50 families is indeed a more acceptable proposal than 75 families or no limit at all. We agree with the prospect of ultimately restricting international donations to 15 families, as well as with the proposal to evaluate the implementation of international limits within commercial banks after three years and to continue research in this area in order to remain focused on respect for individuals.	Thank you.
242	Donor Conception Network		5	183	<p>Setting an international limit</p> <p>We agree with a starting point of 50 families and a plan to reduce to 15 or lower over time</p>	Thank you.

243	Board of Health and Welfare (Sweden)		5	184	We find the 50-family limit high, but that this is a good starting point for reducing the limit further. We would like it to be clear from the start what the final limit should be, to give the gamete banks enough time to adapt. What the final limit should be needs to be discussed, bearing both supply, demand and ethics in mind. Important that each MS can still have their own national limits.	Thank you.
244	Fertility Europe	EU 50 family transitional limit			50 families limit is reasonable only if it is transitional, so the monitoring of access impacts must be real, not rhetorical. Reductions must not occur before donor supply and affordability stabilize The ultimate limit should be defined by formal consultation with recipients, donor-conceived people and donors, so we suggest avoiding using the number of 15 without the survey following providing the information (informed consent).	Thank you. The working group considers that it is necessary to provide a general direction for the ultimate limit, while acknowledging that further research is needed and leaving room for a revision of the number. Therefore, the 15-family limit was kept in the paper.
245	Laura Fernández Olmedilla		5	191-192	I totally agree with the maximum international limit of 15 families per gamete donor.	Thank you.
246	Michael Scholtes		5	183-197	We had an internal discussion in Germany November 2025 in the society of private sperm banks, the maximum of 15 families stays the realistic, defendable number. Starting with 50 families is a foul compromise, not taking into account, seriously enough, the well-being of the offspring. If the present list in Appendix 1 is applied, why is this number of 50 proposed? It may be clear that the media will interpret this proposition as widening of the number of offspring, very unwise!	Thank you for these insights into the operations of German banks. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties. The proposed EU-wide limit should not be compared with current national limits, as the paper states "The proposed international limits are not intended to replace national limits, but rather to complement them. Current

						national limits should still be upheld if they are lower."
247	Solomütter Deutschland e.V.	Input from the German association for Single mothers by choice			<p>Solomütter Deutschland e.V. assesses international limits on the number of families per donor primarily from a child-welfare perspective. We explicitly welcome the recognition of psychosocial harms associated with high offspring numbers for donor-conceived people and donors, including uncertainty about origin, overwhelm from large donor-sibling networks, restricted contact options, and feelings of commodification. Acknowledging these factors is an important step, as they have long been underweighted in regulatory debates. We also support defining limits by the number of families rather than the number of children. This approach respects reproductive autonomy within families, avoids unintended restrictions on the use of cryopreserved embryos, and provides greater clarity for all parties. Allowing donors to set lower individual limits is likewise a meaningful expression of self-determination. However, the proposed initial limit of 50 families per donor remains far too high from a child-welfare perspective. The clear discrepancy between the preferences expressed by organisations representing donor-conceived people, typically two to ten families, and a threshold of 50 families should be given significantly greater regulatory weight. The lived perspectives of donorconceived people, particularly regarding identity development, relationship dynamics, and the experience of genetic connectedness, require stronger protection. Solo mothers have a particular interest in transparent origins and in realistically manageable contact with the donor and donor siblings. Very high limits undermine sustainable relationships and can negatively affect a child's emotional security. Children cannot consent to the conditions of their conception, which creates a specific duty of protection. We therefore prefer a binding limit of a maximum of 10 families per donor. As</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>

					<p>a pragmatic European compromise, a limit of up to 15 families can be supported, provided that counting is family-based, a cross-border registry is in place, and binding information, monitoring, and enforcement mechanisms apply. Arguments based on administrative complexity, data protection, higher treatment costs, or a potential shift toward private donation do not justify the absence of strict donor limits. Implementation challenges are not an argument against necessary safeguards but rather highlight the need for coordinated European infrastructure and effective oversight. Ethical protection of children must not be contingent on price or market dynamics, and the ethically responsible option must not become the more expensive or less accessible one. Sustainable solutions lie in transparent regulation, robust counselling, and strengthening the donor pool, not in the extensive use of individual donors.</p>	
248	Paths to Parenthub		5	183	<p>Whilst we would be supportive of an immediate family limit of 50 imposed on gamete banks, here at Paths to Parenthub we believe this number should be significantly lower (in the region of 25-30 families immediately). We also feel that reduced limits should be implemented far more quickly than the three year time frame suggested by ESHRE at first point of review. Ultimately, Paths to Parenthub would also support a limit if 15 families (or lower) per donor internationally.</p> <p>As previously noted, a number of gamete banks worldwide have already self imposed family limits well below 50, while continuing to recruit donors successfully, offer donor gametes at accessible rates, and remain competitive within the private market.</p> <p>Furthermore, we fully support comprehensive counselling for both donors and recipients, with specific focus on the implications of donation and, in particular, the impact of the current lack of</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>

				<p>international family limits. As highlighted in the HFEA Patient Survey (2025), up to one third of UK parents using imported donor gametes were unaware of the wider implications of using a donor whose gametes were also being used across multiple countries. We feel this confusion/lack of awareness is often compounded by parents not understanding the difference between individual country jurisdiction limits and those on an international level. Furthermore, gamete bank websites are often ambiguous and misleading when referring to family ‘limits’ often using language such as ‘average’, ‘goal of’, ‘aim to’ which lack clarity and finite numbers or statistics to back up such claims.</p> <p>This lack of awareness and transparency continues to be unacceptable.</p>	
249	BCRM - Bristol Centre for Reproductive Medicine	ESHREs recommendations for a 50-family limit across the EU should be lower from the start		<p>My opinion is that an initial family limit of 50 is too high. While I understand that the aim would be to reduce this to a family limit of 15, with a review of the recommended limit every 3 years. I think it needs to be a much smaller limit from the start with a more frequent review of the limit. As stated in the ESHRE position paper where stakeholders have been asked for their views on family limits, it is the donor banks, who have a financial interest in the outcome of this debate, who have suggested higher limits. If the majority are for significantly lower limit, ESHRE should start with a family limit that is lower. At the very least I believe newly recruited donors (i.e. those yet to start donating) should immediately have a lower limit applied to them than 50. The 50-family limit could apply to those already donating/donated. This would hopefully bring a more rapid transition to lower family limits.</p> <p>If using Eurostat (https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Fertility_statistics) data the fertility rate for the EU in 2023 was 1.38 live births per</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>

				<p>woman. If a 50-family limit is applied and 1.38 is used to calculate the potential number of siblings this would allow, its 69 children. A cohort of 69 siblings is too high when considering the welfare of the donor conceived child, the donor and donor recipients undergoing treatment. With regards to the donor conceived child there is a potential for emotional trauma when finding out how many half siblings they may have. This shock may continue throughout their lives due to ancestry testing, with donor conceived people finding more and more siblings potentially over a period of decades when you take into account frozen embryo storage. Donor conceived children in large cohorts are unlikely to be able to form meaningful relationships with so many, meaning what could be a supportive network turns into some other sense of loss or disconnection. I appreciate that for those seeking fertility treatment the use of 1.38 live births per woman may not be representative of this population. You could argue it could be less and therefore sibling cohorts would be smaller as there will be some patients who are not successful with their treatment and therefore take a family slot and contribute 0 live births. Conversely it could be higher, for example when considering same sex female couples seeking treatment and both women wish to carry a child each. Ultimately the limit of 50 families still allows these high number sibling cohorts to potentially come about.</p> <p>If you consider the donor, they may be overwhelmed by requests from dozens of biological children wanting information about them/contact. Whilst the donor is counselled at donation about the family limits it maybe difficult for the donor to comprehend what impact such large sibling cohorts may have on their future lives. Managing relationships, boundaries, or even polite rejection for that many people could be an immense emotional and logistical burden. This argument, which is in the ESHRE position paper, should mean a lower</p>	
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				<p>family limit is immediately used.</p> <p>Many of the patients I work with, where I am based in the UK, do import donor sperm from European sperm banks. Whilst we tell recipients of the family limits, I am unsure that as a recipient of donor sperm, that they can comprehend the impact on their potential child or themselves of finding out about large sibling cohorts when their main focus at that time will likely be choosing a donor that fits that and having that most wanted child. Whilst I understand the reduction of family limits may limit the pool of donors available to recipients, it is potentially in their child's best interest to do so. I have no issue with cross-border imports/exports as long as family limits are still applied as it allows recipients of donor gametes to have a wider range of donor banks and potentially ethnically diverse donors to choose from.</p> <p>Large sibling cohorts also increases the possibility of recessive genetic diseases occurring. Whilst a smaller family limit in no way prevents this from happening and doesn't alter the prevalence as stated in the ESHRE position paper. If a donor unknowingly carries a recessive genetic condition that wasn't screened for (or wasn't known at the time), a large family limit means this gene could be passed to a vast number of children before it is discovered. Where a child is born with a disease and it is later found the donor is carrier the resultant need to manage multiple families i.e. giving them sufficient information and support e.g. via counselling, is a burden to both the donor bank and clinics whose patients have used the donor. Smaller families reduce the burden and associated cost on managing these issues.</p>	
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250	Annemieke Hoek	Setting international limits			<p>We do not agree with the ESHRE position to immediately introduce a EU limit to 50 families (see all the arguments above). We propose, an immediate limit to 15 families coupled to a donor. If the results of an European ESHRE Survey under donor conceived individuals results in a further limitation (see above) than this limit should be introduced in later time(within e.g. 2 years)</p> <p>Line 192: We do not agree with a gradual decrease in number of families coupled to a donor as this is not in line with the ethical position of the ESHRE (stated in line 155). There should be a clear timeline, with deadlines in order to perform and analyze the proposed survey, amend the position paper accordingly (e.g. 2 years)</p> <p>We acknowledge that indeed waiting times for recipients will increase, this will increase the pressure for clinics in reproductive medicine to start or put effort in their own donor banks. We also acknowledge that prices of donor sperm from these commercial donor banks will rise. The ESHRE should encourage fertility clinics to put more effort in recruitment of gamete donors.</p> <p>Moreover, there are alternatives for recipient parents: they can ask men in their own social network If men are willing to donate specifically for their family-tobe, and via their reproductive medicine clinic, this can be managed, with infection screening, genetic screening, cryo-preservation, quarantine and treatment etc.</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>
251	Stichting Donorkind	Setting international limits			<p>We do not agree with the ESHRE position to immediately introduce a EU limit to 50 families (which is to high see all the arguments above) or a gradual decrease. If prospect parents or donors do not want to acknowledge the rights of children they should not make any children.</p> <p>If organizations of professionals are not willing to</p>	<p>Thank you.The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is</p>

					acknowledge the rights of children they should not be in the business of making children.	considered to balance the concerns raised by different parties.
252	Dutch Society of Obstetrics and Gynecology (NVOG)	The 50-family limit			<p>In this context, we diverge from the position paper regarding the proposed initial limit of 50 families per donor. This threshold is considered unacceptable by the vast majority of Dutch gynecologists, who generally advocate for a substantially lower limit, typically ranging from 12 to 25 families per donor.</p> <p>We strongly support further systematic research into the well-being of children conceived through gamete donation, with particular emphasis on identifying the factors that most significantly influence their long-term outcomes. Nevertheless, given existing indications—especially those relating to the formation of extensive donor-related networks resulting from the repeated use of individual donors—we argue that, in the absence of robust empirical evidence, policy and practice should be guided by the precautionary principle of non-maleficence. From a practical and clinical perspective, a limit of 50 families per donor is therefore considered excessively high.</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>

253	Australian and New Zealand Infertility Counsellors Association ANZICA	General			<p>The Australian and New Zealand Infertility Counsellors Association (ANZICA) welcomes ESHRE’s leadership in addressing the critical and complex issue of international donor family limits. We strongly support the in-principle aims of the draft position paper, particularly its explicit prioritisation of the interests and wellbeing of donor conceived persons (DCP) and its recognition of the need for international coordination in this area.</p> <p>Notwithstanding this support, ANZICA has serious concerns regarding the proposed interim limit of 50 families per donor. In our view, this figure is excessively high and risks undermining the very objectives the paper seeks to advance. An interim limit set at this level may unintentionally legitimise the continuation of large-scale donation practices by gamete banks, rather than signalling a meaningful shift toward donor-conceived-centred policy.</p> <p>ANZICA considers that beginning with a high interim limit weakens the ethical intent of the proposal. While we acknowledge that lower limits may be more challenging to implement, starting from a reduced family number would more clearly affirm the gravity of the psychosocial, relational, and identity impacts associated with large donor sibling groups. A substantial gap between an interim limit of 50 families and the stated goal of 15 families also creates a real risk that downward adjustment will be resisted over time, particularly in the face of commercial or access-based pressures. For this reason, ANZICA would advocate for an initial international limit of 25 families per donor as a more proportionate and protective starting point.</p> <p>Greater clarity is also required regarding how any transition to the proposed endpoint of 15 families</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>
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				<p>would be achieved. The draft paper does not sufficiently address questions of enforcement, accountability, or timeframe, all of which are essential if interim limits are not to become entrenched in practice.</p> <p>ANZICA strongly endorses several other elements of the draft position paper, including the justification for donor family limits based on the long-term interests of donor conceived persons and donors, the emphasis on improving compliance and addressing unregulated donation, and the proposal to limit the period between first and final donation to 20 years. These measures reflect a thoughtful engagement with ethical and psychosocial considerations.</p> <p>We also note the clear divergence in perspectives identified in the paper between stakeholder groups. The finding that donor conceived persons, donors, and recipients consistently favour much lower family limits than gamete banks accords with our clinical and counselling experience. In Western Australia, for example, donors and recipients are generally supportive of the existing five-family global limit. These perspectives reinforce the importance of ensuring that policy development is guided primarily by those most affected by donor conception practices, rather than by commercial interests.</p> <p>Finally, we note that very large family numbers imply levels of donation that are unlikely to be consistent with altruistic motivations. This sits uneasily with the Australian context, where gamete donation is unpaid and grounded in ethical principles that emphasise social responsibility and donor welfare.</p> <p>In summary, while ANZICA supports the principles and many of the recommendations articulated in the ESHRE draft position paper, we cannot support the</p>	
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					<p>proposed interim limit of 50 families per donor. Even as a transitional measure, it remains inconsistent with a donor-conceived-centred approach. Concerns about access to gametes, while important, should be addressed through alternative strategies that do not compromise the wellbeing of donor conceived persons, their families, or donors themselves.</p>	
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254	Lisa Ransome	Setting an International Limit		<ul style="list-style-type: none"> • The intention to set an EU based recipient family limit is applauded. It is acknowledged the ability to currently implement a true international limit on donor offspring families, is unable to be effectively managed due to no single authority in place. • A limit on the number of FAMILIES is agreed, as limiting recipient parents to a number of children, reduces reproductive autonomy of those accessing donor conception for family building. It is also suggested family is defined by the number of adults within the relationship irrespective of sex and gender, meaning if there is a same sex-couple they are identified as a single-family unit rather than two separate recipients. • It is agreed donors should be made aware they can set a reduced number of recipient families than the maximum family allowed. Additionally, this should be clearly identified on consent documentation to reduce coercion from gametes banks to donate to the maximum number of families. Furthermore, donors should also be made aware prior to donation they are able to withdraw consent to the ongoing utilization of their donated gametes, however also aware of the limitation this can only include those gametes which have NOT been used to create embryos. Once embryos are created the recipient families may continue to utilise them to build their families. • The temporary family limit of 50 is opposed. A limit of 50 families, even for the proposed potential 3-year period, can still lead to excessive numbers of donor offspring for a single donor, particularly contextual to the knowledge of not limiting recipients to only 1 child. A limit of 50 still has the potential to see a donor-offspring pool of over 100 siblings. It is suggested the limit be reduced to 30, with a reassessment within 12-18th months of the feasibility and then further reduction to the 15 EU wide family limit. • Additionally, with the intention of setting an EU limit 	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>
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				<p>for donor families, consideration should also be placed for the number of families whereby an EU based donor bank (oocyte or sperm) can transfer gametes for treatment outside of the EU limits. E.G. Should a long term 15 family limit be set within the EU, then consideration should be placed for gametes to be transferred outside of the EU to no more than 5-10 families (total of 20- 25 families total internationally). With strengthened EU laws, auditing of donor banks for complying with these numbers, could still feasibly sit within the remit of EU authorities, and sanctions provided to banks who do not comply with these total limits.</p> <ul style="list-style-type: none">• A limit on the timeframe for the use of donor gametes is applauded to reduce the generational gap between donor offspring. However, a reduction to 15 years is suggested, contextual to families still being able to use the donor gametes for siblings, which could be up to a 10-year gap in some families, meaning with a 15 years allocation limit, the potential for sibling age gaps could still reach 25 years.• Yes, efforts to increase the donor pool should be undertaken. The advertising for this, should be effectively managed and oversight provided by the EU legislature to ensure unethical practices are not being undertaken by donor banks, including but limited to coercion through financial gain, or misinformation regarding becoming a donor, and the lifelong implications and impact for the donor and their families. It is noted that with reduction in the donor family limits, combined with awareness of choice for further reduction in these limits, more people may be more open to donation of their gametes. Concerns have been raised in countries where limits, and also disclosure requirements have changed regarding a reduction in willing donors, however generally this has not come to fruition, as such it would likely be the same in the wider EU.	
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255	Anonymous	Offspring Limits			<p>I welcome and strongly support this paper. It is an important step forward in addressing the challenges surrounding donor offspring limits. However, the draft proposes starting with a global limit of 50 families per donor, with a gradual reduction to 15. While I welcome the recognition that lower limits are necessary, I believe the initial threshold of 50 is far too high. Setting such a generous starting point risks undermining the very objective of protecting donor-conceived individuals from large genetic networks. The bar should be set higher from the beginning—for example, a direct limit of 25 families worldwide—so that the policy immediately reflects the principles of child welfare.</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>
256	Donor Conceived UK		5	183-184	<p>Donor Conceived UK strongly objects to the proposal of a 50-family limit. Such a threshold is unacceptably high and fails to prioritise the long-term welfare of Donor Conceived People (DCP). It is notable that this figure aligns with the current self-imposed limits of several gamete banks. This raises legitimate concerns about the extent to which proposed limits are being shaped by commercial practice rather than by the rights, interests, and lived experiences of Donor Conceived People (DCP). Gamete banks benefit financially from maximising the number of families created per donor, and this commercial incentive should not be allowed to determine regulatory standards. Donor offspring limits exist to mitigate harm, not to formalise existing industry norms. A limit set at this level risks entrenching large donor sibling networks and transferring the long-term social, psychological, and medical consequences onto Donor Conceived People (DCP), who have no voice or agency in these decisions.</p>	<p>Thank you. The feedback on the proposed limits was discussed extensively within the working group. The group decided to go forward with the limits proposed in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>

257	Donor Conceived UK		5	191-192	<p>Donor Conceived UK notes that ESHRE ultimately supports a maximum international limit of 15 families or fewer per gamete donor. We therefore question why this level is not adopted from the outset.</p> <p>Introducing an initial limit of 50 families, with the intention of reducing it at a later stage, risks entrenching a threshold that may prove difficult or politically unfeasible to revise downward. Experience in regulatory policy demonstrates that once higher limits are established, they often become the de facto norm rather than a transitional measure.</p> <p>In the UK, a 10 family limit is imposed per donor by the regulator. However, the majority of DCP members of our organisation feel that this limit is too high, with many of our members finding it difficult to navigate large numbers (17, 20, etc.) of half siblings. Donor Conceived UK would like the proposed 15 family limit to be reconsidered and revised to a lower number.</p> <p>If the long-term objective is a limit of 15 families or fewer, Donor Conceived UK strongly urges that this standard be implemented from the beginning, ensuring that DCP are afforded meaningful protection without delay and avoiding the creation of unnecessarily large donor sibling networks in the interim.</p>	<p>Thank you. The feedback on the proposed approach was discussed extensively within the working group. The group decided to go forward with the approach presented in the initial draft, as the different aspects highlighted in the stakeholder feedback were already taken into consideration in the initial drafting and the proposed approach is considered to balance the concerns raised by different parties.</p>
258	Viville Stéphane		5	195	<p>“after three years” is that mean this document should be revised every 3 years?</p>	<p>Thank you. The reference to 3 years was removed to leave the timeline for reduction up to the regulators.</p>
259	Donor Conceived UK		5	195	<p>Donor Conceived UK considers a three-year delay before evaluating whether the 50-family limit can be reduced to be entirely insufficient. Such a lengthy period risks creating unnecessarily large donor sibling networks, with significant long-term implications for DCP.</p> <p>Decisions about donor offspring limits have lifelong consequences for DCP, including the management of genetic relationships, potential consanguinity risks, and the challenges of navigating extensive sibling networks without full disclosure or information.</p>	<p>Thank you. This section of the paper was rephrased and it was clarified that the limit should be reduced further, rather than that it should be assessed whether it can be reduced further. In addition, the reference to 3 years was removed to leave the timeline for reduction up to the regulators.</p>

					<p>Waiting three years before reviewing the limit fails to prioritise the rights and welfare of Donor Conceived People (DCP), effectively placing them at the end of the policy timeline rather than at its centre.</p> <p>We therefore urge that any limits be reviewed and enforced immediately, with mechanisms in place for rapid adjustment, rather than deferring evaluation for multiple years. Early implementation of the lowest safe limit, consistent with the protection of DCP must be the standard.</p>	
260	Cryos International Sperm & Egg bank		5	196-197	<p>We welcome this recommendation and are prepared to contribute to further research on establishing the optimal limit, ensuring that the proposed 15-family limit can be revised in line with updated evidence. It is essential, however, that any future adjustment safeguards broad and equitable access to screened donor gametes, so that all individuals and families who rely on donor treatment can continue to do so without unnecessary barriers.</p>	Thank you.
261	Anonymous	Setting an international limit			<p>A transition limit is proposed but no indication is given about what standards or criteria will be looked at. So when will the limit be increased or lowered? As there is already no evidence provided for the limit of 50 families, what kind of evidence will lead to a change in the limit? I assume that if no, or no relevant research has been performed, the limit of 50 remains?</p>	<p>Thank you. This section of the paper was rephrased and it was clarified that the limit should be reduced further, rather than that it should be assessed whether it can be reduced further. In addition, the reference to 3 years was removed to leave the timeline for reduction up to the regulators.</p>
262	Human Fertilisation and Embryology Authority (HFEA)				<p>The HFEA would be happy to participate in any further discussions about family limits, We note:</p> <ul style="list-style-type: none"> • The proposed limits are significantly higher than the UK 10-family limit, so the UK system would remain more restrictive and we have no plans to increase the limit in the UK. • A consistent EU-wide approach could support transparency for UK patients using imported gametes but we would need Government advice on how this could be applied outside the EU. • Any differences between EU-wide and UK limits 	<p>Thank you for sharing these insights into the implications for the UK. Regarding the last point, the position paper states "Gamete banks that already operate below a 50-family limit are recognised for their good practice and encouraged to maintain it."</p>

					would require ongoing clarity for UK clinics handling imported gametes and for patients. <ul style="list-style-type: none"> • We would welcome clarity in any guidance on any new limit to ensure that recommended limits are not interpreted as a benchmark that could unintentionally encourage clinics or gamete banks operating with lower limits to raise them. 	
263	Annemieke Hoek	Setting international limits			Line 198; we agree to call upon the donor banks to self-impose limits. But we set the limit to 15 for the time being, till further survey of donor conceived individuals propose other limits.	Thank you.
264	London Sperm Bank		6	198-200	We support the call for banks to self-impose limits and clinics to collaborate only with banks that apply them. We suggest strengthening this by recommending that importing jurisdictions require demonstrable bank-level controls (auditable policies and distribution logs) as a condition of market access.	Thank you. The working group considers that this level of detail goes beyond the scope of the paper.
265	Paths to Parenthood		5	198	<p>Until obligatory international limits are introduced, ESHRE calls on gamete banks to self-impose the recommended family limits, and on fertility clinics to collaborate only with banks that apply these proposed limits.</p> <p>Here at Paths to Parenthood, we believe this is a strong and necessary position and that this responsibility should also explicitly extend to fertility professionals more broadly.</p> <p>If we act collectively and choose to support/promote only those gamete banks that are self limiting and adhering to best practice, this will help set a high standard across the sector and encourage others to follow. Intended parents often assume that a gamete bank is reputable if their clinic works with them, and that their clinic has undertaken appropriate due diligence on their behalf.</p> <p>Sadly, many parents report feeling deeply let down</p>	Thank you.

					when they discover, often after their children are born, that some gamete banks impose no effective family limits. This lack of transparency can have devastating consequences for donor conceived people and their families.	
266	Donor Conceived UK		5	198-200	Donor Conceived UK is deeply concerned by the reliance on voluntary compliance in this recommendation. While ESHRE calls on gamete banks to self-impose the recommended limits and on fertility clinics to collaborate only with compliant banks, we do not believe this will occur in practice without a fundamental paradigm shift and legislative reform. Commercial incentives strongly favour higher donor offspring limits, and there is no mechanism to ensure that clinics prioritise the long-term welfare of DCP over business interests. Without legal requirements or robust regulatory oversight, voluntary adherence is unlikely to be sufficient to protect Donor Conceived People (DCP) from the creation of excessively large donor sibling networks and the associated social, medical, and psychological consequences. Donor Conceived UK therefore urges that any meaningful protection for Donor Conceived People (DCP) must be enshrined in law, not left to voluntary action by clinics or gamete banks.	Thank you. The position paper does not rely on voluntary compliance. The call on gamete banks to self-impose limits is made in addition to the policy recommendation to the EU to impose a mandatory EU-wide limit, not as an alternative to a limit enshrined in law. It aims to encourage changes in practice as soon as possible, given the long duration of EU legislative processes.
267	Michael Scholtes		5	198	Knowing the internal discussions within commercial institutions, this will be shrugged off. Just by showing implemented legislation, restricting the number of offspring, the board of directors will change their policy. The first action will be to look for possibilities to circumvent any regulation. This means an enforcement will be necessary to improve the present situation. Accreditation of European donor banks by the ESHRE should be a precondition for a license to sell/use SoHo's.	Thank you. EU regulations do not allow ESHRE to decide which gamete banks can be licensed to sell SoHOs. ESHRE can only provide policy recommendations to the EU and good practice recommendations to clinics and banks. Mandatory limits need to be set by legislators.

268	Anonymous	Setting an international limit			Why is there a time limit? Again, no justification is offered. I am not aware of any research showing that there is a problem with large age gaps. Will time limit also be imposed on the use of frozen embryos (with or without donor gametes)? This point again demands an explanation of the underlying reasoning rather than the presentation of some gut feeling that many people will not share.	Thank you. The justification for the time limit is provided in the section on psychosocial aspects, namely to avoid difficulties in contact between donor siblings with large age gaps, as well as to reduce the likelihood that donors are already deceased by the time that offspring is old enough to consider seeking contact.
269	Cryos International Sperm & Egg bank		5	202-203	This statement lacks supporting rationale. It is unclear why a 20-year limit is considered appropriate for a “generation,” and no evidence or ethical reasoning is provided to justify restricting distribution after this period.	Thank you. The justification for the time limit is provided in the section on psychosocial aspects, namely to avoid difficulties in contact between donor siblings with large age gaps, as well as to reduce the likelihood that donors are already deceased by the time that offspring is old enough to consider seeking contact.
270	CRYOGONIA CRYOPRESERVATION BANK	Notion of donor conception			The use of donation should be regarded as a form of assisted procreation intended to help create <u>individual</u> families. Recipients tend, in certain cases, to adopt the notion that this could substitute for a means of creating family relations with the donor (acting as a ‘father’) or forming extended family ties with other same-donor families (‘siblings’). Informed consent of interested recipients should include clear explanation of the nature of their choice and the limitations it pertains. In this sense, the adoption of any time limit for the use of donor gametes is irrelevant.	Thank you. Informed consent provisions are considered outside of the scope of this paper.
271	CRYOGONIA CRYOPRESERVATION BANK		5	202	This could be applied only in the case of ID-Release donors, even though the concept is based on the misconception that donors and donor conceived children should establish contact and create social relationships.	Thank you. The working group does not consider a distinction between ID-release donors and non-ID-release donors relevant in this context, since donor anonymity can no longer be guaranteed in light of possibilities to identify donors through direct-to-consumer genetic testing.

272	JUAN JOSÉ GUILLÉN			202	<p>Regarding the use of cryopreserved gametes over extended periods (within the proposed 20-year limit), we wish to highlight a safety aspect often overlooked. In the context of the new SoHO Regulation, which emphasizes donor vigilance, the passage of time can enhance safety rather than diminish it. A sample used 10- or 15-years post-donation allows for a 'longitudinal screening' of the donor. If a proper follow-up system is implemented (e.g., monitoring donors every 5 years until age 50), using an older sample from a donor confirmed to be healthy offers a higher safety profile regarding late-onset genetic conditions than a fresh sample from a young donor whose future health phenotype is yet to be revealed.</p> <p>Therefore, long-term storage—when paired with active donor follow-up— should be viewed as a quality assurance mechanism that validates the biological safety of the gametes for subsequent siblings</p>	Thank you. This aspect was added to the paper.
273	The Danish Business Association for Egg and Sperm Donation (BFSD)	On time limits for the use of gametes			<p>ESHRE proposes that gametes should no longer be distributed to new families after 20 years. BFSD believes this proposal merits further discussion, including ethical and medical considerations. Discarding viable, safely stored gametes solely due to time limits raises questions about proportionality, sustainability, and responsible use of medical resources. Any such restriction should be carefully evaluated to ensure it is ethically and medically justified.</p>	Thank you. A sentence was added to the paper to recommend that the 20-year limit should be reviewed after implementation, similar to the proposed family limits.
274	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies		5	201- 203	<p>We understand the justification for no longer distributing gametes to new families after 20 years following the first donation. For clarification, this would not prevent current families from using already purchased vials or cohorts to have a genetic sibling (even if the expiration has passed)? Our position is that this restriction should only apply to new families, thus allowing those families who have already purchased vials or cohorts to use them at any time.</p>	Thank you. Indeed, the paper states that this limit only applies to the distribution to new families. Furthermore, a clarification was added to the paper that all proposed limits should be implemented in such a way that it does not impact ongoing treatments.

275	Board of Health and Welfare (Sweden)		5	202	Good suggestion	Thank you.
276	Aoife Campbell		5	201-203	Agree	Thank you.
277	Donor Conceived UK		5	201-203	<p>Donor Conceived UK notes that a 20-year limit on distributing gametes after the first donation may appear reasonable as an approximate generational timespan, but we are concerned that 20 years is a very long time in practice.</p> <p>We also question how this aligns with the UK's 55-year storage limit for gametes, which allows embryos and gametes to be stored and potentially used decades later. Without clear harmonisation between these policies, there is a risk of confusion, regulatory gaps, and inconsistent protections for DCP, who may face unexpected genetic connections many years after their conception.</p> <p>Donor Conceived UK recommends that any timespan for limiting the use of gametes be carefully evaluated in conjunction with national storage laws, and that the primary consideration must remain the long-term welfare and rights of Donor Conceived People (DCP).</p>	Thank you. Indeed, the current UK policy does not align with this recommendation. In case such a policy is introduced at EU level, the implementation in case of cross-border exchanges will be have to be clarified.
278	Donor Conception Network		5	202	<p>Setting an international limit</p> <p>We agree that there should be a maximum length of time for donor gametes to be used. We want to avoid large age gaps between half siblings/siblings and make it likely the donor is potentially still alive when the child reaches maturity. We would prefer under 20 years but accept this may not be workable. What about embryos created with donor gametes? And what about double donation? Do these need specifying?</p>	Thank you. We have added a sentence to specify that the implementation of the proposed limits (time and family limits) should not affect ongoing treatments or the use of embryos that were already created.
279	BCRM - Bristol Centre for Reproductive Medicine	ESHREs proposed 20 year limit on distribution of donor gametes to new families			<p>In the UK donors can consent to 55 years of sperm storage and 55 years of embryo storage so theoretically half siblings could continue to appear for a century, although you would hope this to be very unlikely. I therefore support the idea that there should be a time limit for when the donor is distributed to new families. I feel ESHRES proposed 20-year limit is still too long. In the UK donors can donate up to age 45. If a family is</p>	Thank you for sharing these concerns. We have added a sentence that the proposed 20-year limit should be reviewed after implementation with a view to potential reduction.

					<p>offered the gametes for the first time 20 years later, the donor would be age 65. By the time the donor conceived child is 18 and can find out identifying information about their donor (I appreciate rules maybe different across other EU countries) the donor could theoretically be 83 and potentially deceased. Whilst many donor conceived children may decide not to contact their donors, or do but do not have a relationship with them, the longer the donation period the less choices both to donor conceived individuals and the donors themselves with regards to their biological parent/child.</p>	
280	Annemieke Hoek	Setting international limits Duration of distribution of donor gametes			<p>Line 201-204: we do not agree with the EHSRE position that donor gametes should not be distributed to new families after 20 years (after the first child is born), to avoid large age gaps between donor siblings. In natural conceived families children are on average 2-3 years apart. In order to ensure that donor conceived individuals are more or less of the same age category no more than 10 years of donor gamete distribution should be the limit. Moreover, in case distribution is set for 20 years, donor conceived persons, will be confronted with an ever increasing network of halfsiblings for more than 20 years, this might lead to stress and mental harm, as one's identity is partly based on the size of the network of half siblings. Furthermore, as stated above, also this issue of duration of distributions should be part of an European survey of the ESHRE under donor conceived individuals; in line with the ethical position the ESHRE stated in line 155</p>	<p>Thank you for sharing these concerns. We have added a sentence that the proposed 20-year limit should be reviewed after implementation with a view to potential reduction.</p>
281	Stichting Donorkind	Setting international limits Duration of distribution of donor gametes			<p>In natural conceived families children are on average 2-3 years apart. In order to ensure that donor conceived individuals are more or less of the same age category no more than 10 years of donor gamete distribution should be the limit. Moreover, in case distribution is set for 20 years, donor conceived persons, will be confronted with an ever increasing network of</p>	<p>Thank you for sharing these concerns. We have added a sentence that the proposed 20-year limit should be reviewed after implementation with a view to potential reduction.</p>

					<p>halfsiblings for more than 20 years, this might lead to stress and mental harm, as one's identity is partly based on the size of the network of half siblings.</p>	
282	Dutch Society of Obstetrics and Gynecology (NVOG)	The distribution limit of 20 years			<p>We also diverge from the position paper with respect to the proposed donor distribution period of 20 years. It is important for donor-conceived individuals to have clarity about the size and scope of their network of half-siblings. For this reason, we recommend considering a shorter initial distribution period, for example 10 years, with the possibility of extension only if future research demonstrates that a longer period does not negatively affect the well-being of donor-conceived individuals.</p> <p>In addition, we believe that donors themselves should be given the option to set a personal maximum limit on the number of families or offspring conceived using their gametes.</p>	<p>Thank you for sharing these concerns. We have added a sentence that the proposed 20-year limit should be reviewed after implementation with a view to potential reduction. The recommendation that donors should be given the option to set personal limits was already included in the paper.</p>
283	Department of Clinical genetics, Rigshospitalet, Copenhagen	Setting an international limit			<p>I agree that a 15 family limit is the goal at some point, and the possibility for the donor to set a lower limit for his/her gametes. I think 20 years is too wide a window, would prefer 10 years, after that only families with children from that donor can use the donor again. For the donor, it would mean a foreseeable expiration date on new families.</p>	<p>Thank you for sharing these concerns. We have added a sentence that the proposed 20-year limit should be reviewed after implementation with a view to potential reduction.</p>
284	Viville Stéphane		5	201-208	<p>This is without taking into account the fact that embryos can be stored for additional year. Lets imagine a first donor conception than a last one 20 years later with forzne embryos used, let say 10 years later....</p>	<p>Thank you for sharing these concerns. We have added a sentence that the proposed 20-year limit should be reviewed after implementation with a view to potential reduction.</p>
285	Donor Conception Network		5	204-208	<p>Setting an international limit Is there a significant shortage?</p>	<p>This is difficult to state for certain. It is known that at the moment, a big proportion of gamete supply is provided by a few large banks that are operating with high self-imposed limits or without any limits, so a significant impact on supply can be expected.</p>
286	Viville Stéphane		5	201-208	<p>I believe the word "affordability" should be used</p>	<p>Thank you. This was added as suggested.</p>

287	Aoife Campbell	Donor Recruitment			<p>Is there a case to be made for establishing a Donor Bank on a National/EU level similar to blood or organ banking and distribution?</p> <p>It could be argued that the need for donor gametes is a public good, necessary to provide required fertility care, yet it is left solely in the hands of private enterprise. Other aspects of fertility care, such as IVF labs form part of health care services provided at state level by member states. Such a state lab could provide donor gametes at cost, and form part of the approach to limit the number of patients who take an unregulated route to obtain donor sperm.</p>	<p>Thank you. A recommendation to encourage public and non-profit involvement in donation programmes was added, in line with the wording of the SoHO Regulation.</p>
288	Fertility Europe	Ethical donor recruitment			<p>Our concerns are commercialisation and pressure on donors.</p> <ul style="list-style-type: none"> -prohibition of volume-based incentives -mandatory education on long-term implications -psychological screening aligned with offspring-contact realities <p>(we suggest linking ESHRE guidelines on donor compensation)</p>	<p>Thank you. We consider these recommendations to be outside the scope of this paper.</p>
289	Fertility Europe	Equity of access and financial burden on patients			<p>The document should acknowledge a need for:</p> <ul style="list-style-type: none"> -mitigation strategies for cost increases and waiting times -safeguards for already marginalised patient groups -monitoring of cross-border reproductive travel burdens 	<p>Thank you. Some mitigation strategies for the consequences of the limit are already proposed in the paper (gradual reduction alongside efforts to increase the donor pool). Safeguards for marginalised groups and monitoring of cross-border reproductive care travel burdens are considered outside of the scope of this paper.</p>
290	The Danish Business Association for Egg and Sperm Donation (BFSD)	Donor supply and the impact of new EU regulation			<p>BFSD shares ESHRE's concern that restrictive limits, if introduced without accompanying measures, will reduce donor availability. This risk is heightened by the new EU SoHO Regulation, which is expected to increase administrative burdens, constrain donor compensation, and limit donor outreach and marketing.</p> <p>Efforts to increase the donor pool are essential — but must be realistic and aligned with the new regulatory</p>	<p>Thank you for sharing your views.</p>

					framework. Without active support for donor recruitment, shortages are inevitable, leading to longer waiting times, higher costs, higher prices and increased inequality in access to treatment. Ultimately this risks driving increased grey-market pregnancies involving unregistered and untested donors, higher incidence of genetic and sexually transmitted diseases, and significant legal uncertainty regarding the rights and responsibilities of donors, patients, and donor-conceived children.	
291	CRYOGONIA CRYOPRESERVATION BANK	Donor recruitment			Donor recruitment is a challenging process, especially due to the constantly diminishing semen quality, as well as the low acceptance rates. In order to ensure the adequacy of supply, the EU should assist the member countries in establishing campaigns aiming to inform the young candidates, e.g. via TV spots, social media digital videos etc, accentuating the social necessity and positive impact of donation.	Thank you. Communication campaigns and education programmes are already listed as recommendations in the paper.
292	Cryos International Sperm & Egg bank		5	205-208	<p>We agree that maintaining the donor pool is important to ensure access to donor gametes and to prevent reliance on unregulated sources. One potential measure could be financial or logistical support from public authorities to facilitate donor recruitment, including communication campaigns and educational programs, similar to initiatives for critical SoHO supply continuity.</p> <p>It is naive to believe that maintaining the donor pool will be achieved by the current initiative. It is primarily the extensive bureaucracy in the EU that is responsible for the lack of supply. All other things being equal, the market effect of international quotas will lead to a reduced supply of donated gametes.</p>	Thank you. We consider that your recommendation is captured by the current text, which recommends taking similar measures as for the supply continuity of critical SoHO.

293	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)	Egg Donation in United Kingdom		<p>There is a lack of study globally and specifically in the UK. UK Government increased the financial ‘expenses’ to £985 which incentivises low-income women as payments are made as flat sums, not direct reimbursement for travel, accommodation etc. The Department for Health and Social Care did not risk assess the impact of increasing payment rates. The egg retrieval process involves hormonal treatments that can result in the extraction of an excessive number of eggs, often exceeding natural biological limits, raising serious health concerns. Women who donate their eggs are not legally required to undergo genetic screening, which poses additional risks. While fertility clinics (often owned by private equity firms) profit from this practice, the NHS bears the costs of treating related health issues.</p> <p>Between 2011 and 2020, HFEA data shows that 4,147 egg donors came from the most deprived areas, compared to 3,007 from less deprived ones, with payments for egg donation rising from £250 to £985 per cycle. There is an alarming increase in young donors, with 5,158 women aged 18-25 registered from 2000 to 2022.</p> <p>Advertisements targeting women to donate their eggs have been seen at Universities, Bus Stops and on the London Underground. These adverts fail to mention health risks and the Department for Health and Social Care has failed to mandate the inclusion of health risks in these advertisements. We believe that adverts soliciting egg donations should be prohibited entirely.</p>	<p>Thank you. ESHRE's position on gamete donor compensation is available here: https://www.eshre.eu/Europe/Position-statements .</p>
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294	Donor Conceived UK		5	204-208	<p>RE: “Efforts should be made to increase the donor pool to avoid shortages”. We recognise concerns about access to treatment and the risks associated with unregulated private donation. However, increasing the donor pool should not be treated as a numbers exercise alone. Any efforts must prioritise the rights, welfare, and long-term wellbeing of Donor Conceived People (DCP).</p> <p>Shortages are often driven by policy and practice choices, including limits on information, lack of support for donors, and inconsistent regulation, rather than an inherent lack of willingness to donate. Addressing these underlying factors is more effective and ethical than simply seeking to recruit more donors. Crucially, policy responses should not frame DCP as a risk to be managed (for example, by preventing parents from seeking alternatives), but as individuals with lifelong interests in accurate records, identity information, and protection from exploitation. We therefore support:</p> <ul style="list-style-type: none"> • Well-regulated donation pathways, with robust record-keeping and guaranteed access to donor information for DCP. • Improved support and counselling for donors, recipients, and donor-conceived families, including honest information about long-term implications. • International cooperation and oversight to reduce cross-border and informal practices that undermine regulation. • Policy reform informed by donor-conceived voices, ensuring that solutions to shortages do not compromise human rights. <p>Discouraging unregulated donation should be achieved by strengthening ethical, transparent systems, not by lowering standards or sidelining the interests of the people most affected</p>	<p>Thank you. While we acknowledge the importance of these points, we consider these recommendations to be outside the scope of this paper.</p>
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295	Annemieke Hoek	Setting international limits Avoid shortage			Line 204-209: we agree with the ESHRE statement that similar measures should be taken as for the supply continuity of critical SOHO e.g. facilitating public participation in donation programs etc. But we refrain from the notion that gametes are critical SOHO perse. Gametes can be used for donation, but recipients have alternatives for their reproductive wishes by asking persons in their own network to be their donor. If gametes are defined as critical SOHO, then the pressure to increase the number of families coupled to a donor will increase and lead to larger half sibling networks again.	Thank you. The position paper does not state that gametes are critical SoHO or call for defining gametes as critical SoHO.
296	Stichting Donorkind	Setting international limits Avoid shortage			But we refrain from the notion that gametes are critical SOHO perse. Gametes can be used for donation, but recipients have alternatives for their reproductive wishes by asking persons in their own network to be their donor.	Thank you. The position paper does not state that gametes are critical SoHO or call for defining gametes as critical SoHO.
297	Menno Hofman		5	204	As I see it one of the efforts should be around knowledge about donor conceived who want to become donor themselves. At the time I went to the clinic I wasn't sure it would be possible.	Thank you. We consider that this is one of the points that could be addressed in the recommended education programmes. Since we have decided not to go into detail on what these education programmes should entail, it was not added specifically to the paper.
298	Donor Conception Network		5	204-208	Setting an international limit We would add a recommendation for fertility education and awareness.	Thank you. We consider this point to be outside the scope of this paper.
299	Astrid Indekeu		5	208	It might be valuable to state explicitly that communication campaigns and education programmes should address potential donors as well as intending parents (on the possible implications of multiple siblings)	Thank you. We have mentioned the importance of information and counselling for intended parents, including on the reasoning behind limits, in the introduction. The communication campaigns mentioned here are specifically for donor recruitment.

300	Donor Conception Network		5	204-208	Setting an international limit We would suggest producing educational resources/marketing materials explaining clearly WHY the limits are in place - the priority given to the wellbeing of DCPs and the need for clarity, accountability and a level of certainty for all those concerned. This could be an opportunity for the EU to position itself as a global leader in this to encourage other countries to follow.	Thank you. We have mentioned the importance of information and counselling for intended parents, including on the reasoning behind limits, in the introduction. The communication campaigns mentioned here are specifically for donor recruitment.
301	Fertility Europe	Transition rules for existing patients			The paper should address the transition rules for: -patients currently in treatment -patients with embryos already created -patients mid-cycle when limits are introduced	Thank you. A recommendation was added that the proposed limits should be implemented in such a way that they do not affect ongoing treatments or the use of embryos that were already created.
ESHRE position and policy recommendations: Monitoring compliance						
302	Board of Health and Welfare (Sweden)		5	211	MS should be encouraged to have national registries, and referring to article 58.10, respect other MS limits when distributing gametes.	Thank you. A recommendation was added for the establishment of national registries in case an EU-wide registry is not feasible. The point that Member States should respect each others' limits was not added, since this paper is specifically about creating a common international limit.
303	Melinda Ildiko Mitranovici		5	211	an EU-wide donor registry to monitor donations within the EU, including gamete imports from non-EU countries is mandatory	Under the SoHO Regulation, aggregated activity data reporting will be mandatory (i.e., how many donors, straws, total number of offspring from donation). A centralised EU-wide registry that allows monitoring offspring numbers per individual donor is currently not mandatory.
304	CECOS (Centre d'Etude et de Conservation des Oeufs et du Sperme) Federation	The follow up of gamete distribution			It is essential to have comprehensive data on the number of births per donor: Europe should track the use of each gamete distribution, to know whether IUI or IVF was used, whether embryos were stored, and whether this was followed by a pregnancy and/or birth. This requires each country to maintain a donor registry.	Thank you.

					We strongly support the proposal of “monitoring compliance” line 210.	
305	Dutch Society of Obstetrics and Gynecology (NVOG)	Further additions			To ensure compliance with these standards, the establishment of a centralized registration system encompassing all gamete banks within the European Union is essential. One potential practical mechanism would be the introduction of a European quality label for banks that explicitly commit to these principles, combined with legal accountability in cases where agreed-upon limits are exceeded. Finally, we recommend that any future directive provide clear and harmonized guidance on the screening of donors for genetic conditions and infectious diseases.	Thank you. A centralised EU-wide registry is proposed in the paper. Guidance on donor screening is considered outside the scope of this paper.
306	Anonymous	European Donor Register			Given the reality of cross-border movement of gametes and reproductive treatments within Europe, enforcement of donor offspring limits cannot be effectively achieved without a centralized mechanism. Embedding a European donor register within the framework of the EU SoHO Regulation would provide transparency and oversight across member states, ensure effective enforcement of limits, and support counselling by giving women access to verified information. Importantly, such a register would also guarantee openness regarding the actual number of children and families per donor, thereby strengthening trust and accountability.	Thank you.
307	Cryos International Sperm & Egg bank		6	211-212	Cryos notes that donor registries already exist in several countries, but the requirements for which donor personal data must be recorded vary significantly. We therefore support the establishment of an EU-wide donor registry. A harmonized registry would streamline administration and better safeguard donors’ GDPR rights. At present, the diversity of local rules and documentation requirements means that donors must complete multiple, differing legal information and consent forms across jurisdictions, which is confusing and burdensome for donors. An EU registry with	Thank you.

					standardized core data and interoperable consent management would reduce complexity while respecting national laws on access (including identity disclosure) and ensuring privacy-by-design.	
308	Anonymous	Transparency of Commercial Donor Banks			Many commercial donor banks currently fail to disclose to donor-conceived individuals the actual number of offspring created from a single donor. This lack of openness undermines the rights of donor-conceived children to understand their genetic background and complicates enforcement of offspring limits. To address this, ESHRE should consider either the establishment of a European donor register or the introduction of a binding reporting obligation for donor banks. Such an obligation could be modelled on the SoHO framework, where specific items are legally required to be shared. Applying a similar principle here would ensure that donor banks must disclose key data—such as the number of families and children per donor—thereby guaranteeing transparency, accountability, and enforceable limits across Europe.	Thank you. Information for donor-conceived people on the donor and donor siblings is not the core topic of this paper, so the working group decided not to go into further detail on this. The paper already includes a recommendation that it should be explored whether this registry could give access to some non-identifying information to donors and donor-conceived people.
309	JUAN JOSÉ GUILLÉN			211	We endorse the creation of an EU-wide donor registry solely for monitoring purposes and safety. However, we explicitly oppose the suggestion that this registry could be used to reveal the donor's identity to offspring (lines 215-216). We firmly believe the registry must strictly protect donor privacy and anonymity. Instead, we propose implementing a 'Voluntary Consanguinity Check' tool (Match/No Match system). This functionality would allow two partners to verify if they share the same donor code receiving a simple 'Incompatible/Compatible' result, without ever revealing the donor's identity or personal data. This approach is supported by: 1. Privacy Protection: This tool solves the medical concern of accidental consanguinity without crossing the red line of identity disclosure. It proves that it is possible to ensure offspring safety while fully respecting the donor's right to anonymity.	Thank you. The focus of this paper is on donor offspring limits and the recommendation for an EU-wide donor registry aims to allow for monitoring the adherence to such limits. It does not recommend donor identity-release.

					2. Historical Precedent (Dor Yeshorim model): A similar 'anonymous compatibility' system has been used successfully for decades by the Ashkenazi Jewish community to prevent Tay-Sachs disease. In that model, couples check compatibility before marriage without revealing their individual carrier status. The EU registry should emulate this strategy: prioritizing public health safety (preventing consanguinity) without compromising the privacy of the parties involved."	
310	Fertility Europe	Registry access: patient rights vs privacy			The registry discussion focuses heavily on donor privacy and GDPR compliance, but recipients and donor-conceived people bear long-term consequences and have no choice about data existence, so we suggest: -patient representation in registry governance -transparency about what information may become accessible in the future safeguards against patients being affected or blamed for registry-related breaches	Thank you. The working group decided not to go into further detail on the governance of the proposed registry in this paper due to the limited scope.
311	Donor Conception Network		5	211	Monitoring compliance We agree with setting up an EU-wide donor registry, including imports	Thank you.
312	The Danish Business Association for Egg and Sperm Donation (BFSD)	The indispensable role of an EUwide registry			BFSD strongly supports the introduction of a central EU donor, treatment, and donor-conceived children registry, as proposed by ESHRE. An EU-wide limit cannot be effectively implemented or enforced without an EU-level mechanism for oversight and coordination. Such a registry is essential to ensure transparency across borders, enable traceability when new medical or genetic information emerges, and support compliance with family limits while allowing free movement within the EU. At the same time, BFSD highlights that pregnancy-slot mechanisms already play an important role in managing family limits in practice, as they are allocated before distribution and thereby reduce the risk of limits being exceeded. Without pregnancy slots, compliance would be significantly more dependent on other factors, such as effective systems and timely	Thank you.

					<p>pregnancy reporting by clinics.</p> <p>These tools are an important complement to regulatory oversight — but they cannot replace a central EU registry, which remains necessary to ensure consistency, compliance, and accountability across member states.</p>	
313	CRYOGONIA CRYOPRESERVATION BANK	Centralized monitoring of donors			<p>The SoHO regulation provides an excellent opportunity to create a centralised framework for monitoring donors and donor gamete use in all EU countries. The installation of a European Registry, codifying each donor in a unique form, would facilitate the efficient application of the donation limits within the EU.</p>	Thank you.
314	Annemieke Hoek	Monitor compliance			<p>We agree that the EU should set a legal basis for Eu-wide donor registry, including gamete imports from non-Eu countries. Line 233: We agree that “pregnancy slots” should be set in place for clinics and gamete banks, in order not to exceed the number of families coupled to a donor. This should be mandatory before donation.</p>	Thank you.
315	Stichting Donorkind	Monitor compliance			<p>The EU should set a legal basis for Eu-wide donor registry and prohibit gamete imports from non-Eu countries. Especially since we think that prospect parents and donors should meet and make arrangements beforehand.</p>	Thank you. The working group has decided not to add a recommendation to restrict imports from non-EU countries, as long as the EU limits and standards are upheld.
316	Michael Scholtes		5	212	<p>It will be clear that any regulation will be difficult and will take some time to be finalized not to speak of being implemented. The easiest will be on a national level, EU-wide is a herculean task, with non-EU countries not feasibly.</p> <p>It is not realistic to expect commercial donor banks outside the EU to comply. If you do not have oversight and do not have the guarantee of permanent access to those data, you will be fooled. The ESHRE and EU should be free of influences of external legislations.</p>	Thank you. The working group has decided not to add a recommendation to restrict imports from non-EU countries, as long as the EU limits are upheld. This should be ensured through the system for oversight over imports that is already envisioned in the SoHO Regulation in the same way as for all other standards.

317	Michael Scholtes		5-6	211-235	<p>The EUMAR tries to induce transparency in MAR. It is not complicated to design a monitoring system for germ cell donors. GDPR will shape this monitoring. Taking into account the voluntary character of germ cell donation, after proper informed consent, DNA-fingerprinting of donors could be a backup, to insure complying with EU laws. Designing a model is relatively simple, how to enforce is more difficult. Where the data are stored (how long), who has access will be a matter of political debate. First all relevant data must be identified, codified. This cannot be a major problem; bitcoins also see to have some data security. Designing this system, means scrutinizing possible sources and means of abuse.</p> <p>It would not be a surprise to see the future funding occurring as a major barrier.</p>	Thank you for sharing your insights.
318	Marilyn Crawshaw		5	210-217	<p>It's not clear to me how monitoring will ensure adherence. Taking the recent Belgium example, the legal limit of 6 children per woman was breached extensively so it seems clear that some mechanism to prevent this happening is needed</p>	Thank you. Indeed, ensuring adherence requires effective enforcement by the competent authority. However, the working group considers monitoring a necessary first step for ensuring adherence, which was also lacking in the recent Belgian case.
319	Marilyn Crawshaw		5	214-215	<p>There is evidence to support the need to collect biographical information about the donor for release to DCP. I strongly urge the inclusion of this</p>	Thank you. This recommendation is considered outside the scope of this paper.
320	Aoife Campbell	Donor Conditions			<p>If the establishment of an EU wide donor registry was successful, could such a register be used for the secondary purpose of responding to Donor Conditions? For example, to identify any children impacted by situations such as the recent case whereby sperm from a donor with a rare cancer-causing gene was used for the conception of at least 67 children?</p>	Thank you. This was added to the paper.

321	Donor Conception Network		6	218-219	Monitoring compliance We are unclear exactly what this sentence means “Before an EU wide donor registry is in place, gamete banks should already be obliged to comply with the limit in their own distribution of gametes.”	Thank you. This recommendation was added to avoid that the lengthy process of establishing an EU-wide registry should not delay the implementation of the limit at gamete bank level. An EU-wide registry is needed to ensure that donors cannot surpass the limit by donating to multiple banks, but large donor sibling groups are nowadays often created from donations to a single bank and this practice can be changed even before an EU-wide registry is in place.
322	Anonymous	Monitoring compliance			Why should a bank do this when there is no clear evidence that a high limit is harmful? The same applies to donors. Moreover, how can banks verify things when they lack the means to do so?	Thank you. These are policy recommendations to the EU, so the proposal is that banks should be obliged to ensure compliance with the EU-wide limit. Banks have a possibility to ensure compliance within their own distribution through operating with pregnancy slots, which are only released if a clinic reports back that there was no pregnancy and there are no embryos/gametes from that donor left in storage for this pregnancy slot.
323	Donor Conception Network		6	222	Monitoring compliance Could a route be created within the register for private donor arrangements to be recorded voluntarily? This could help with donors who wish to donate both privately and through a clinic/bank.	Thank you. The working group considers that this goes beyond the scope of the paper.
324	Donor Conceived UK		6	221-224	Donor Conceived UK strongly agree. Donors should be required to provide a signed declaration disclosing all previous donations and confirming their commitment to refrain from making private (unregulated) donations.	Thank you.
325	Mary Wingfield		6	222-224	“If the number of families resulting from previous donations is not known, banks/clinics should not accept donors for further donations”. This seems to contradict the subsequent section which states that	Thank you. This sentence was changed to "If the number of families to whom gametes from previous donations were distributed is not known, banks/clinics

					<p>“In the absence of knowledge on whether a live birth took place, the number of families to whom gametes were distributed should be counted to ensure that the family limit is never exceeded.” If we accept the number of families to whom gametes were distributed as equivalent to the number of families born in one scenario, we should be consistent and also apply this to donors who can provide details of the number of their donations distributed but who don’t know whether anyone was born from those donations. .</p>	<p>should not accept donors for further donations."</p>
326	Cryos International Sperm & Egg bank		6	222	<p>This requirement may be overly restrictive. For example, “known donors*” may donate to multiple women, and men may already have children with several partners, making it difficult to fully prevent private donations. Clarifying the scope and feasibility of this declaration would help ensure it is realistic and proportion-ate.</p> <p>*A donor whose identity is known to the recipient - for example, a male friend donating to a female couple.</p>	<p>Thank you. Known donations should be included in the count for the family limit. Having children with several partners is considered different from gamete donation. The donor's own children (of which they are the legal parent) should not be included in the count for the family limit.</p>
327	JUAN JOSÉ GUILLÉN			221	<p>We disagree with the recommendation to automatically reject donors if the outcome of previous donations is unknown (lines 222-223). A donor should not be penalized for administrative gaps or lack of reporting by third parties. Excluding willing, screened donors due to missing data from external clinics is an inefficient waste of resources that exacerbates donor shortages. The lack of data is a systemic failure, not a donor compliance issue. Instead of blocking the donor, we propose that the focus should be on enforcing mandatory reporting obligations. Regulations must compel fertility centers and recipient patients to report live birth outcomes to the original gamete bank. If a 'compliance gap' exists, the solution is to fix the reporting loop (e.g., conditioning access to future treatment on reporting past outcomes) rather than proactively discarding valid donors based on an assumption of risk</p>	<p>Thank you. This sentence was changed to "If the number of families to whom gametes from previous donations were distributed is not known, banks/clinics should not accept donors for further donations.", so if gametes were distributed to fewer families than allowed under the limit, the donor will not be blocked.</p>

328	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		6	221-224	Signed declarations should already be in place, however, sperm donor can provide different names at different clinics and if this is an EU requirement, men donating their sperm can go outside of the EU to the UK or other continents to offer their sperm. We observe some racial undertones of the desire, from one publicised account of a prolific sperm donor, to “bleach Africa”.	Thank you. Indeed, a signed declaration is only one aspect of ensuring compliance. Donors going outside the EU are outside of the scope of EU regulations.
329	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies		6	221- 224	<p>Donors who have participated in sperm donation programs elsewhere are not eligible to enter the CCB sperm donor program. Egg donation, however, is treated differently from sperm donation due to the medical nature of the process.</p> <p>We request that ESHRE reconsider this section to allow egg donors that have donated elsewhere to still join our donor program if the donor can provide the number of donations (cycles) they previously underwent. If the recommended cycle maximum (6) has not been reached, it should be allowable for an egg donor to enter the program. In absence of outcome information from donations that occurred elsewhere, a reasonable data driven formula should be used to establish the existing number of family units.</p> <p>Egg donation is a more invasive and medically complex procedure, and it is not uncommon for donors seeking a better experience to transfer between programs while still adhering to established limits for donation cycles and family units. Unlike sperm donation, which is non-invasive, time-limited, and typically completed within a single program, egg donors often relocate and work with multiple fertility clinics before completing all six (6) recommended cycles. This is because egg retrievals involve significant medical coordination and can span several years. These fundamental differences justify a distinct approach for egg donors compared to sperm donors.</p>	Thank you. It is not the intention of this position paper to prevent egg donors who have already undergone a donation cycle from donating at another establishment. However, at least the number of families to which oocytes from the donor were distributed in previous donations should be known and pregnancy slots should be blocked for these families if the outcome of these donations is not known.

330	Cryos International Sperm & Egg bank		6	229-235	<p>Cryos understands that the SoHO Regulation introduces a requirement for clinical-outcome registration. We respectfully urge the implementing bodies to specify “live birth” as the primary clinical outcome for medically assisted reproduction with donor gametes and to make live-birth reporting a mandatory, harmonised data element across Member States.</p> <p>This clarification is essential to provide a robust and comparable basis for monitoring family and offspring limits and to avoid underestimation when pregnancy outcomes are unknown.</p> <p>At present, this approach is not feasible in Denmark: local legislation requires notification only of confirmed viable pregnancies, not live births, and there is no clear legal basis to obtain systematic live-birth information from patients or authorities. Consequently, counting families based on live births cannot be implemented at this time. We therefore encourage the EU to establish a harmonised legal framework and GDPR-compliant data flows that enable clinics to follow up with patients and report live-birth outcomes to gamete banks across jurisdictions.</p>	<p>Thank you. This is only a requirement if clinical-outcome monitoring is needed during an application for SoHO preparation authorisation, so it is not a requirement for general practice.</p>
331	London Sperm Bank		6	228-235	<p>We support counting distribution to families (e.g., “pregnancy slots”) when live birth outcomes are unknown. We suggest adding guidance that reporting from clinics back to banks should be time-bounded and standardised, to avoid delays that can inadvertently allow continued distribution.</p>	<p>Thank you. The sentence "Clinics are encouraged to follow up on the pregnancy outcomes of treatments with donor gametes and report back to banks to allow for the release of pregnancy slots where possible." was added.</p>

332	The Danish Business Association for Egg and Sperm Donation (BFSD)	Pregnancy slots		<p>BFSD believes pregnancy slots play an important role but pregnancy slots must be addressed at institutional (EU) level and address some of the below mentioned challenges (the list is not exhaustive)</p> <p>Centralised EU governance of pregnancy slots A competent EU authority should centrally allocate and manage numbered pregnancy slots, including clear rules on slot volume based on realistic medical outcomes (e.g. miscarriage rates) and the relationship between pregnancies and live births.</p> <p>1. Centralised patient matching, verification, and reporting Pregnancy slots should be linked to verified, ID-identified patients, with treatment outcomes confirmed by the treating clinic or physician. This includes closing the regulatory gap between a registered pregnancy and a donor-conceived child.</p> <p>2. Clear definition of “family unit” and ownership of pregnancy slots Harmonised EU guidance is needed on how family units are defined when couples separate, including:</p> <ul style="list-style-type: none"> o Management of embryos created prior to separation o Ownership and transferability of pregnancy slots (e.g. biological mother vs. both parents) o Prevention of artificial inflation of “families per donor” due to differing national laws <p>3. Full traceability of embryos and donor material Robust requirements must ensure reporting and tracking of all embryos created and stored, with traceability back to the specific straw used, across clinics and borders.</p> <p>4. Cross-border treatment, citizenship, and data governance A coherent EU framework is required to address:</p> <ul style="list-style-type: none"> o Non-EU nationals and fertility tourism from outside the EU o EU cross-border treatment (which country a 	Thank you. The working group does not consider it necessary for an EU authority to centrally allocate pregnancy slots. In order to avoid that the family limit is ever exceeded, the slot volume should be equal to the applicable family limit. Details regarding the definition of a family, traceability rules, etc. are left up to regulators to determine.
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					<p>pregnancy slot belongs to)</p> <ul style="list-style-type: none"> o Patient and donor-conceived child identification in registries, in compliance with GDPR <p>Today, these complex issues are largely left to donor banks and clinics without clear regulatory guidance. Introducing formal family limits and pregnancy slot requirements without simultaneously addressing the above will further weaken an already fragmented and inefficient system. The current lack of coordination drives unnecessary administrative costs for clinics, banks, authorities, and patients—reducing access and transparency. BFSB therefore welcomes and encourages structured dialogue on these issues prior to the implementation of EU-level limits.</p>	
333	Fertility Europe	Counting families			<p>we strongly support this approach of counting families, not children and allowing slot release only when there is certainty that no child was born and no embryos remain</p> <p>safeguards are needed for: clear accountability for reporting failures, legal protection for patients if slots are miscounted and transparency for patients about their “slot status”</p>	Thank you.
334	JUAN JOSÉ GUILLÉN			228	<p>We fully support the methodology of counting every distributed family as a 'potential family' (the 'pregnancy slot' system) until a negative outcome is confirmed. This conservative approach is the industry standard for ensuring limits are never breached. However, we must highlight that this system relies entirely on the efficient reporting of negative outcomes. If clinics or patients fail to report that a treatment did not result in a live birth, these 'slots' remain locked indefinitely, artificially restricting the donor and wasting valuable gametes. Therefore, this recommendation reinforces our previous point: reporting must be mandatory. ESHRE should advocate for binding obligations on clinics to report treatment failures and miscarriages promptly. The 'pregnancy slot' system is only sustainable if there</p>	Thank you. The working group decided against proposing a legal reporting obligation for clinics, since patients may also be lost to follow-up for clinics. Instead, the sentence "Clinics are encouraged to follow up on the pregnancy outcomes of treatments with donor gametes and report back to banks to allow for the release of pregnancy slots where possible." was added.

					is a robust mechanism to release those slots when no child is born, ensuring the donor pool is optimized rather than paralyzed by administrative silence	
335	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		6	225-235	Limits within international operating clinics should already be monitoring and restricting based on country limits (from country of origin of donor) and monitoring live births. As noted in the paper, "This system is already in place in many gamete banks, who require clinics to purchase a "pregnancy slot" for each recipient, which is then only released if it is known that the donation did not lead to a child." We support this action as a pre-existing requirement that should be upheld and practised already.	Thank you.
336	Aoife Campbell	Pregnancy slots			In my experience, the release of these slots to other families, if the first holder is unsuccessful in having a child, is difficult. They function very well to limit the number of people using a donor at a given time, but I suspect, they also function to artificially hold slots. If a person is unsuccessful and stops seeking further treatment they often fall out of contact with fertility services. These slots cannot be used for anyone else and so block that donor. The release of these slots could prove valuable in easing pressure on donor availability if a limit of 50 families is imposed, considering that reported live birth rates for fertility treatment are below 50%.	Thank you. The sentence "Clinics are encouraged to follow up on the pregnancy outcomes of treatments with donor gametes and report back to banks to allow for the release of pregnancy slots where possible." was added.
337	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies	Regulating Family Units			We agree it is important to set a limit on the number of family units allowed per gamete donor; however, we recommend using a data-driven formula for monitoring family limits given reporting may be inconsistent or less reliable across gamete banks.	Thank you. The working group considers that a data-driven formula is not sufficient to ensure that the limit is never exceeded.
338	California Cryobank LLC, and CCB DEB, LLC dba Donor Egg Bank USA, both CooperSurgical, Inc. (CSI) Companies		6	228- 235	We request that ESHRE rely upon clinic reporting of live birth data to determine distribution of donor gametes. Widespread utilization of the pregnancy slot process would drastically limit access of donor gametes to potential families, essentially shutting down this path to family. Currently, many gamete programs use	Thank you. The working group considers that a data-driven formula is not sufficient to ensure that the limit is never exceeded.

					<p>reasonable, evidence-based methods to meet family unit limits without relying on a pregnancy slot system. Pregnancy slots are not a reliable mechanism because outcome reporting is often inconsistent across donor programs and difficult to verify. Instead, limits should be managed through data-driven models informed by industry experience and historical outcome data. California Cryobank has operated since 1977 and has collected extensive data on donor cycles, gamete distribution, and resulting family units. In addition, Donor Egg Bank USA, established in 2012, maintains robust data collection and reporting through SART, providing highly accurate and validated outcome information. Together, this long-standing experience enables us to apply predictive models that account for clinical pregnancy rates, miscarriage rates, and typical usage patterns, ensuring compliance with recommended family limits while maintaining transparency and operational feasibility.</p>	
339	Francoise Shenfield			233	The “pregnancy slot” terminology might be rephrased	Thank you. As the term "pregnancy slot" refers to a widely used and established system, it was decided to keep it.
340	SARA DALLA COSTA	Donor Gametes Cross - Border			<p>The absence of shared European standards makes it difficult to apply national limits on the number of children per donor in cross-border settings. For example, Italian law limits the number of children per donor to ten, while most gametes used in Italy are sourced from foreign banks, particularly in Spain (in Italy there are no donors, and both the state and clinics—public and private—must rely on foreign banks, especially Spanish ones). Without a shared European donor registry, clinics cannot verify compliance with this limit, as they do not know how many donation cycles have been performed, how many gamete units have been distributed, or how many children have been born from the same donor in other countries. This makes it very difficult for Italian clinics to ensure the ten-child limit is respected.</p>	Thank you. The working group decided against including recommendations on the implementation of national limits in this paper, since the scope is on international limits.

				<p>It also remains unclear whether national limits in exporting countries apply only to children born domestically or also to those born abroad. This lack of clarity creates a structural compliance gap and underlines the need for clearer, harmonized standards across Europe.</p> <p>While awaiting a European donor registry, the Position Paper could provide guidance on how both exporting and importing clinics and banks can ensure compliance. For instance, exporting banks could provide a self-certified document showing the number of children already born from that donor, while receiving clinics could submit an annual report indicating how many children were born from each donor.</p>	
341	Lisa Ransome	Monitoring Compliance		<ul style="list-style-type: none"> • As noted in previous responses, legislated monitoring and compliance of donor banks within the EU is strongly encouraged. This monitoring would need to include EU limits, potential international limits, and also the import of donor gametes from outside of the EU for potential recipient parents use. • Strong consideration should be placed for a central register of birth through donor conception, for linking purposes. Precedent is set in many countries of this working effectively, and with positive outcomes for all those who are within the donor process. Additionally, with the increasing access to at-home DNA kits, there is no true anonymity any longer, as such facilitating donor linking through a managed register centralised in Europe, can only be advantageous for the health and wellbeing of all those involved, particularly donor conceived people. • Obligation for donor banks to keep a record prior to an EU register is endorsed • Donor declarations are also endorsed, with cessation of use if number of allocated families cannot be confirmed by the donor banks • It is endorsed that those donor banks which are 	Thank you. These comments are all in line with the contents of the paper.

					linked should maintain the required donor family limit, and comply with this across their combined sites and not the individual site's locations. <ul style="list-style-type: none"> • Gamete allocation should not exceed the number of families, irrespective of confirmation of live births. An allocation should ONLY be reallocated in the event of a signed declaration from the initial recipients of cessation of treatment without a child, along with the declaration from their treating fertility specialist. 	
342	Stichting Donorkind	Setting international limits			Any guideline without enforcement is an empty shell.	Thank you for sharing your views.
343	London Sperm Bank		5	210-235	Monitoring compliance. This is one of the most important sections. We recommend adding an explicit mitigation paragraph that connects monitoring to action, including: <ul style="list-style-type: none"> • a defined rapid-response process (case review timelines, decision thresholds, donor hold/suspension procedure); and • a staged-release model for new donors (e.g., initial global distribution tranche before full release). Also consider recommending that regulators require banks (including non-EU exporters) to maintain a single global donor identifier across all distribution channels to reduce “multi-bank” leakage risk.	Thank you. The handling of cases where a genetic condition is detected is considered outside the scope of this paper. While the working group agrees that a single global donor identifier would be useful, it is not clear how such an identifier could be created and implemented in practice.
344	Astrid Indekeu		6	235	Add something about possible legal consequences for breaching donor limits?	Thank you. Since the paper recommends the implementation of an EU-wide limit within the SoHO Regulation, the legal consequences should be the same as for breaching other standards of the SoHO Regulation, i.e., suspension or withdrawal of the authorisation to operate as a SoHO establishment.
ESHRE position and policy recommendations: Counselling and informed consent						
345	Anonymous	Monitoring compliance			What is the point about information provision mixed up with the family limit?	Thank you. The recommendations on information and counselling were removed and a reference to the ESHRE good practice recommendations on

						information provision was instead added in the introduction.
346	Annemieke Hoek	Counselling and informed consent			Line 237-239; We agree counselling and written informed consent for donors and recipients should be open about the large number of families and offspring	Thank you. This point of the paper was moved to the introduction.
347	Lisa Ransome	Counselling and Informed Consent			<p>More in-depth psychosocial counselling should be considered for ALL donors and recipient with the following points being addressed by qualified mental health professionals with registration within the appropriate regulatory body of the various international fertility counselling bodies (IE: BICA, ANZICA, ASRM-MHPG, ASPIRE, & ESHRE)</p> <ul style="list-style-type: none"> • donors and recipients being informed of the current family limits imposed and where the limitations lie, including in the inability for current true international donor limits to be set, due to the challenges with regulating this across ALL international borders. • While donor banks may issue donor gametes within the designated country limit (E.G. UK or Australia 10 family limit) this allocation of gametes may still breach the donor limit of the individual country, even with reduced EU family limits • That at present, a donor donating at multiple donor banks cannot be appropriately regulated due to limitations with correspondence and cross checking between countries, and donor banks • Donors should also be adequately and appropriately psychological counselled of the psychosocial implications for their own children, and their own family of origin when becoming a donor, and how to inform family they have become a donor • Recipients should be adequately counselled regarding the benefits of disclosure from a young age regarding their child being donor conceived 	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and decided to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on the points to address in counselling were added.

348	Stichting Donorkind	Counselling and informed consent			Counselling of prospect parents and donors should be done by independent child- and family-professionals, not by medical- or psycho/social fertility-professionals financially dependent on a clinic. Preferably a donor conceived professional is part of the counselling process. Informed consent can only be done in the whole network of genetically linked families. So there should be protocols to introduces new prospect parents to all existing families and donor.	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on how to organise counselling were added.
349	CECOS (Centre d'Etude et de Conservation des Oeufs et du Sperme) Federation	Informed consent			We share the desire that donors and recipients be informed about applicable offspring limits prior to donation/donor treatment, and that this is stated in a written consent form.	Thank you. This point of the paper was moved to the introduction.
350	Hana Konečná	Non lege artis procedures			I greatly appreciate the work of team member Petra Thorn, a long-standing experienced counsellor. I assume that she drew attention to the need for and desperate lack of counselling, including implications counselling. ESHRE issued a recommendation for good practice in this regard in 2022. The availability of psychosocial support prior to signing the informed consent form for all parties involved and the availability of support after the birth of the child – especially for the child – is deteriorating significantly, even in countries that have been considered models of good standards in this area (UK, D, NL). The International Infertility Counselling Organisation (IICO) also draws attention to this crisis situation in its 2024 statement and calls on treatment providers to take responsibility : „The fertility industry should share responsibility for the provision of high quality psychosocial professional support services. This field is ever evolving but the barriers to responding organically throughout the life stages with appropriate psychosocial skills and knowledge include the lack of financial structures and policies as well as the limited research and practice evidence base and the limited availability of training, in particular for work at later life stages.“	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on this point were added.

					In the draft, ESHRE declares that the most important consideration is the interests of the child: "the wellbeing of donor-conceived people should have the highest priority when determining limits on the number of offspring per gamete donor" (lines 155-156). I therefore expected the text to clearly state that without fulfilling the condition of high-quality, long-term, easily accessible counselling (according to Figure 2. The timeline of donor-assisted conception) , especially for children born in this way, these procedures are non lege artis. In other words, they are a punishable practice.	
351	Anonymous	Counselling			I welcome the inclusion of counselling in the draft and strongly affirm its importance. Counselling is a crucial safeguard to ensure that both donors and recipients are fully informed of the medical, ethical, and psychosocial implications of donor conception. I support ESHRE's emphasis on this aspect and encourage its consistent implementation across Europe.	Thank you. This point of the paper was moved to the introduction.
352	Fertility Europe	Informed consent			Defining standards for 'informed consent' for donors and recipients (we suggest linking ESHRE guidelines on information in gamete donation with additional aspects about the limits). Requirement for re-consent if limits, registries, or access rules change over time	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on this point were added.
353	Fertility Europe	Informed consent			Adding request for standardised, EU-level informed consent requirements, including: o Clear explanation of: - current and future offspring limits - cross-border use of gametes o Registry inclusion and data sharing (Explicit explanation of what happens if limits are reached after embryos already exist) Asking for renewed consent when there is any change, eg.:	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on this point were added.

					<ul style="list-style-type: none"> o limits change o registries are introduced o embryos are transferred across borders 	
354	Donor Conception Network		6	237	<p>Counselling</p> <p>It would be helpful to clarify the reasons for the limits and put that message front and centre including feedback from DCPs and prospective parents to make it clear the drive comes from those directly affected and is not arbitrary or punitive</p>	Thank you. This point of the paper was moved to the introduction, including a specific reference to information about the reasoning behind limits.
355	London Sperm Bank		7	236-239	<p>We support this recommendation. Please consider adding that counselling should cover not only the applicable limit but also:</p> <ul style="list-style-type: none"> • whether the donor is under a staged-release policy; • what happens in the event of a serious genetic concern (donor hold, recall/notification protocols); and • transparency on the donor's potential international distribution footprint (to the extent allowed), so donors and recipients understand the realistic scale and implications. 	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on this point were added.
356	Donor Conceived UK		4-5		<p>There is no reference to the need for psychosocial counselling in the bullet points and we suggest there should be. In our view, it should be compulsory and should be provided by qualified counsellors, with ESHRE setting out relevant qualifications.</p>	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on this point were added.
357	Marilyn Crawshaw		4-5		<p>There is no reference to the need for psychosocial counselling in the bullet points and I suggest there should be. In my view, it should be compulsory and should be provided by qualified counsellors, with ESHRE setting out relevant qualifications. (and see below)</p>	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on this point were added.

358	Donor Conceived UK		6	236-239	Counselling is not simply about providing information on limits, it's about discussing the implications of this.	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on this point were added.
359	Marilyn Crawshaw		6	236-239	Counselling is not simply about providing information on limits, it's about discussing the implications of this. I suggest this needs a little more work (and see my comment above_	Thank you. The working group decided to keep the scope of the paper focused on offspring limits and to remove the recommendations on information and counselling and instead make a reference to this topic in the introduction. So, no further details on this point were added.
360	Solomütter Deutschland e. V.		6	237-239	Our practical experience shows that this requirement is currently not met. In reality, some fertility clinics or sperm banks do not adequately inform women about how many offspring and donor siblings are realistically possible across borders. Information is often vague, minimized, or framed in abstract terms, without making clear that a high two-digit number of genetic half-siblings is a realistic outcome. Many women only become aware of the actual scale years later, often after contacting donor siblings. At that point, the emotional impact can be severe. Women report distress, guilt, and a sense of having made decisions without full knowledge of the consequences for their child. This demonstrates that informed consent in its current form is insufficient and that clear, concrete, and explicit information about potential offspring numbers is essential before donation or treatment.	Thank you for sharing these insights.
361	Cryos International Sperm & Egg bank		6	237-239	Information and counseling for both donors and parents is the right way to handle this issue instead of trying to manage the international quota by regulation, which will just reduce the supply and push even more people out on the unregulated market. We strongly	Thank you for sharing your position.

					emphasize making the limits of 50 and 15 optional, but refrain from setting limits in general, but have trust in reproductive autonomy by letting the parents-to-be choose by themselves, but with full information and counseling and consent. Choosing a gamete donor is not a medical procedure - as little as it is in normal reproduction, it is more like dating. Only in case the recipient is ill, which is very few, for instance not lesbians and singles, who stand for >80% of the demand of donor sperm.	
362	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		6	236-239	Counseling and informed consent - we observe again the very short section regarding counseling and consent and note the lack of curiosity and detail, specifically relating to donor conceived children and this juncture of the proposals, and again notice the significant weighting for the adults in the arrangements.	Thank you for sharing your observations.
363	Astrid Indekeu		6	239	Not only emphasized but (in my clinical experience) also explained.	Thank you. This point of the paper was moved to the introduction, including a specific reference to information about the reasoning behind limits.
Appendix 1: National donor offspring limits in EU/EEA countries						
364	SARA DALLA COSTA	Donor Gametes Cross - Border			Finally, Appendix 1 should clarify whether the maximum number of children applies in total and / or not only within the Member State.	Thank you. We have added a note on this point under the table in Appendix 1.
365	Cryos International Sperm & Egg bank		7	242	Denmark: Maximum number of children per sperm donor Children in 12 families (after 2006), 25 children (for donors before 2006) Maximum number of children per oocyte donor Children in 12 families	Thank you. The information for oocyte donors was added, but details on rules for donors before 2006 were not included.
366	CRYOGONIA CRYOPRESERVATION BANK		7	242	The national quota limit for Greek residents used to be 10 children plus siblings – it has been recently modified to 12 families (for first-time donations after 14/10/2022).	

367	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		7	242-244	Of the 30 countries referenced in Appendix 1. Countries that recommend or limit to between 3-5 families totalled 9 Countries that recommend or limit to between 6-8 families totalled 6 Countries that recommend or limit to 10-12 families totalled 6. We observe that only one country (Germany) from the chosen list of 30 countries allows for the same number of recipient families for one donation of gametes, as is proposed by ESHRE in the Draft Position Paper.	Thank you. Indeed, most countries have lower limits. It should be noted that the proposed limit is an international limit - it introduces an additional limitation and does not intend to replace current national limits.
368	Astrid Indekeu		Appendix 1		I am aware that the UK is not part of EU/EEA, yet it is part of ESHRE, and reference is made to the HFEA. I would suggest to add UK into the table as well as CH, as 2 'outside EU/EEA but involved' countries	Thank you. The UK was added to the table.
Appendix 2: Discussion on EU legal principles						
369	Astrid Indekeu		Appendix 2	262	Suggest add 'often' set within national legislation (or something similar, as in some countries a limit is still a 'recommendation'	Thank you. This was adapted as suggested.
370	Melinda Ildiko Mitranovici		8	260-276	What about recipients from non-EU countries who come to seque donors and treatments in EU Member States?	Thank you. This section of the paper discusses whether the objectives of setting limits could be achieved with national action alone or whether EU-level action is required. Since the case you mention can neither be sufficiently addressed with national nor EU-level action, it was not considered relevant for this discussion.
371	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		8	266	A one donor per family "would imply a 27 family limit at EU level, far surpassing the preferred limit of stakeholder groups." Over half (18) of the 30 chosen countries applied limits of 6 families or fewer. The proposed eventual limit is 40% more.	Thank you. Unfortunately, your point here was not clear to the working group.
372	CRYOGONIA CRYOPRESERVATION BANK		8	265	The general limits should be adopted based on scientific data, i.e. solid statistical models verifying the limit for avoiding consanguinity. According to the minutes from ESHRE campus 'Sperm Banking' 2016, the statistical evidence denoted that offspring number per donor should be 10-100 counted as families, not	Thank you. As deliberated in the discussion of aspects to take into account when determining donor offspring limits, the working group has decided not to solely focus on the risk of consanguinity, but to take

					individual children. [<i>Focus on Human Reproduction, 2016 'Crisis? What crisis?', p.6-8</i>]	psychosocial aspects into account in its recommendations.
373	Cryos International Sperm & Egg bank		8	284-287	<p>While Cryos recognises the need for an EU-wide framework to manage donor-offspring numbers, we wish to underline that access to treatment would be significantly reduced if very low international caps - such as a maximum of 15 families per donor - were introduced. In practice, such restrictive limits would constrain availability for patients who depend on donor gametes and could lead to longer waiting times, treatment delays, increased prices, and reduced cross-border access.</p> <p>We also note that, although increasing the donor pool is proposed as a mitigation, the reality across Europe is that many countries are not self-sufficient in donor gametes. Denmark has become a net exporter precisely because it has been one of the few jurisdictions able to attract and retain a large number of donors. Experience shows that rapidly expanding local donor bases elsewhere has been challenging, despite concerted efforts. Against this backdrop, very low uniform caps risk exacerbating shortages rather than safeguarding offspring welfare.</p> <p>Cryos therefore encourages ESHRE and EU policymakers to consider proportionate limits that preserve access to care, coupled with robust monitoring, transparent outcome reporting (including live-births), and targeted measures to responsibly grow the donor base where feasible. This balanced approach can protect the mental health and dignity of donor-conceived offspring without unduly restricting access to medically necessary treatments.</p>	Thank you for sharing your position. The feedback on the proposed approach was discussed extensively within the working group. Considerations on the impact on access to treatments were already included in the initial draft of the position paper, and the working group still considers that they do not generally outweigh the arguments for introducing an international limit, as long as this limit is implemented gradually and alongside mitigation measures.
374	Stop Surrogacy Now UK (Lexi Ellingsworth) and Surrogacy Concern (Helen Gibson)		9	302-303	We share concern regarding data collection, privacy and consent, particularly regarding donor conceived people who cannot consent to having their data stored from birth, however we reiterate our concern regarding Member States and recommend that international donation is prohibited, gametes and embryo export	Thank you. The concerns regarding cross-border exchange of gametes were discussed within the working group, and it was concluded that a restriction of cross-border exchange is not sufficiently justified, so the overall

					also be banned and that the approach of these proposals be viewed from an alternative framework and perspective that seeks to restrict donor conception across borders, in place of seeking to liberalise with frameworks that actively sanction the practice.	approach of the paper was not changed.
References						
375	Fertility Europe			Ref. 10	the long URL in reference 10 that contains the entire Facebook referral part that is unnecessary to reach the website and may be safely deleted	Thank you. This was adapted as suggested.