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ESHRE reaction to the Council's position on the SoHO Regulation proposal

ESHRE welcomes the timely publication of the Council's negotiating mandate on the SoHO Regulation, which ensures that the process is on track for adoption of the Regulation within the current legislative term.

In particular, we are very pleased to see that the Council has revised the definition of "offspring from medically assisted reproduction", so that this term only applies to born children (article 3(11)). This improves the clarity of the text and ensures that vigilance reporting of pregnancy loss is limited to those cases where it can be of benefit. We hope that the revised definition will be accepted by the Parliament in the upcoming trilogues.

However, there are two aspects where we believe that the changes introduced by the Council would weaken the legislation's positive impact:

Firstly, we are highly concerned about the Council's decision to abolish the hierarchy of guidelines for donor, recipient and offspring protection (articles 56(4) and 59(4)). This hierarchy is essential for the harmonisation of standards across the EU, one of the key objectives of the SoHO Regulation.

Secondly, we regret that the Council chose to remove the possibility for direct submission of activity data from existing national or international registries to the EU SoHO platform (articles 33 and 44). With this change in the legislation, an important opportunity for improving the harmonisation of data collection would be abandoned.

We are looking forward to continuing our engagement with the EU institutions during the trilogue negotiations and we hope that the measures for harmonisation of data collection and treatment standards from the initial Commission proposal can be confirmed at this stage of the legislative process.