

6.9.2023

A9-0250/241

**Amendment 241**

**Nathalie Colin-Oesterlé**  
on behalf of the EPP Group

**Report**

**A9-0250/2023**

**Nathalie Colin-Oesterlé**

Standards of quality and safety for substances of human origin intended for human application (COM(2022)0338 – C9-0226/2022 – 2022/0216(COD))

**Proposal for a regulation**

**Recital 18 a (new)**

*Text proposed by the Commission*

*Amendment*

***(18a) As indicated by the Council of Europe Committee on Bioethics<sup>24a</sup>, it should be possible to compensate donors for any quantifiable expenses and losses, financial or non-financial, that they incur as a result of a donation. When calculating such compensation, SoHO entities should be able to take into account non-financial variables to determine the appropriate level and form of compensation to be given to donors, as long as such compensation complies with the principle of voluntary and unpaid donation laid down in this Regulation.***

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***<sup>24a</sup> Council of Europe Committee on Bioethics, Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors, March 2018. Available at: <https://rm.coe.int/guide-financial-gain/16807bfc9a>.***

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