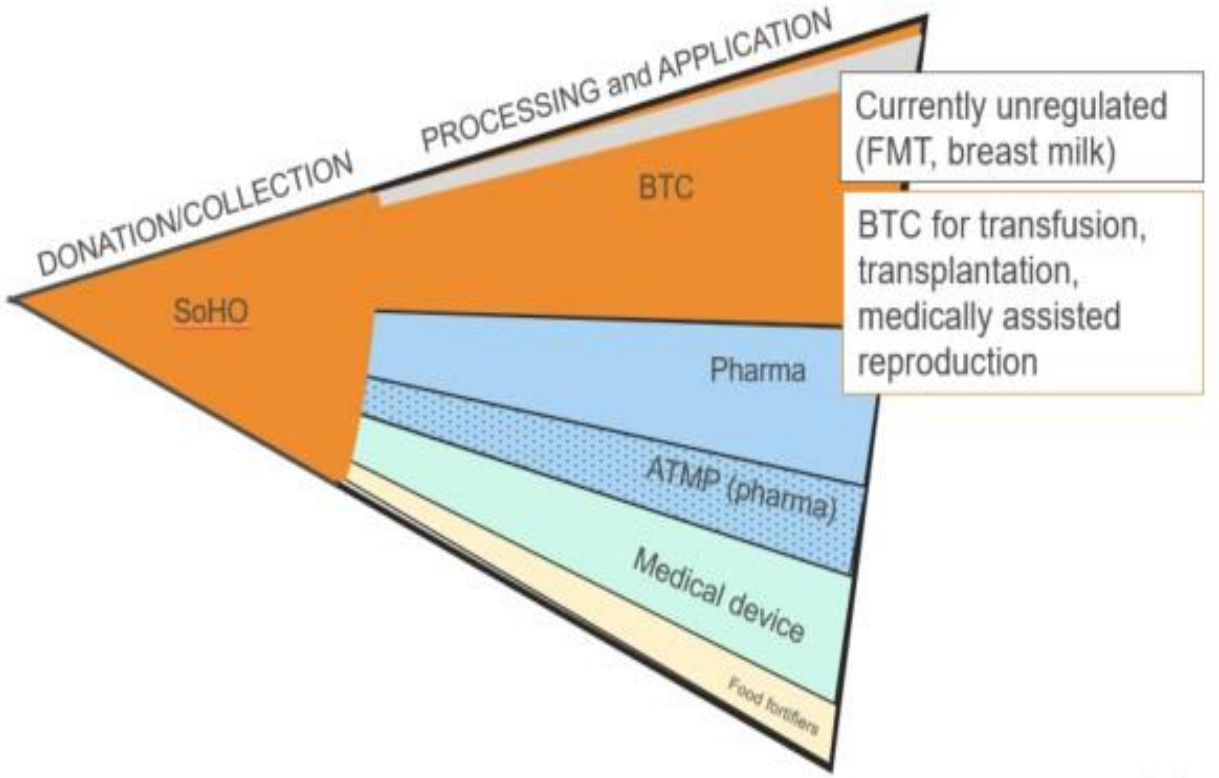
# HS-g-23-50(a) and (b)
# Action grants on the safety and quality of new Substances of Human Origin (Breast Milk-a) and Faecal Microbiota Transplants – b)

EU4Health 2023 Work Programme - Information Session Open Calls For Action Grants

*30 June 2023*

# Background and policy context

- Therapies of human origin with increasing use and value
    - Breast milk (human donor milk) for neonatology (BM)
    - Faecal Microbiota Transplants (FMT) for gastro-intestinal, immunological, and other diseases
- Similar risks than Substances of Human Origin, self-regulations based on standards for SoHO (e.g., blood)
- Currently unregulated at EU-level, new SoHO regulation will fill gap and offer appropriate level of safety and quality for many of these therapies, while allowing affordable access
- Around 200 entities/establishments across Europe have to be prepared to working under the new SoHO regulation




European Commission

# Activities to be funded

This action will bring together sector professionals for BM (a) and for FMT (b) in order to facilitate implementation of new SoHO framework's requirements:

a) Building an expert forum of actors in breast milk and stool banking;

b) Developing common set of draft guidelines based on expertise and existing initiatives - from professional societies, research and publications (Keller&all(FMT), EMBA (BM), EDQM (BM/FMT), … );

c) Future updating of guidelines with/under new EU legislative work;

d) Implementation plan (technical guidelines + oversight provisions);

e) Training and dissemination

Taking account of commonalities and specificities of BM and FMT with other SoHO

# Expected results and impact

The two sub-topics should provide up-to-date guidelines on:

a) technical safety and quality aspects for BM (subtopic (a)) and for FMT (subtopic (b));

b) implementation of the legal requirements by establishments preparing these substances covered by both subtopics and applying therapies based on them.

Create a forum from where key experts including Member States authorities can be engaged also in the future whenever the guidelines need to be updated, or when further advice is needed on their implementation.

Consider coherence with other Union legislative framework, where some BM or FMT can serve as starting materials for other therapies manufactured under other legislative frameworks (pharmaceuticals, food, …)

# Budget and targeted applicants

- **Budget**: EUR 400 000 for each sub-topic
- **Targeted applicants**: civil society organisations (professional associations, foundations, NGO's, …) with expertise in the field of neonatology (topic a-BM) and of gastro-enterology (topic b-FMT)
- Sole participant or consortium
- Open call for proposals (action grants): 1 expected to be signed per sub-topic
- Expected duration of the project: 18 months

- More information: https://hadea.ec.europa.eu/calls-proposals/2023-eu4health-calls-action-grants_en

# Thank you



European Commission