

## Joint Position PRI and IPA Europe

**Subject.** Position Paper on the Scope of Regulation (EU) 2024/1938 on Substances of Human Origin (SoHO) in Relation to Isolated Microbial Strains from human microbiome samples

To the attention of:

SoHO coordination Board

Chair and Co-Chair (NL and EC)

DG Sante: D D2

This paper aims to clarify the implications of Regulation (EU) 2024/1938 on substances of human origin (SoHO), with specific regard to microbial strains isolated from human microbiome samples. The associations PRI and IPA Europe respectfully submit to the attention of the Substances of Human Origin Coordination Board (SCB) the following arguments and regulatory references supporting the position that isolated microbial strains should not fall within the scope of the SoHO Regulation. These strains are already comprehensively regulated under existing sectoral frameworks, including pharmaceutical, food, and cosmetics legislation. In order to support a harmonised interpretation, implementation and application of the SoHO framework and to prevent potential misinterpretation, the Associations propose that this topic should be included in the agenda of a forthcoming SCB meeting. We would welcome the opportunity to present and discuss this position.

Brussels, 20 Mai 2026

### 1. Nature and Characteristics of Isolated Microbial Strains

#### 1.1 Distinction Between Microbiome Samples and Isolated Strains

Isolated bacterial strains (i.e. isolates), even when originating from samples of the human microbiome, are fundamentally different from microbiota samples themselves. The isolation and subsequent banking of a strain constitute a comprehensive risk-mitigation process. This process removes potential pathogens, adventitious agents, and other impurities that may be present in the parent sample, and eliminates all unknown components by retaining only a single, pure, clonal strain (Figure 1 – Isolation process).

## ISOLATION PROCESS OF STRAIN FROM HUMAN MICROBIOME SAMPLES

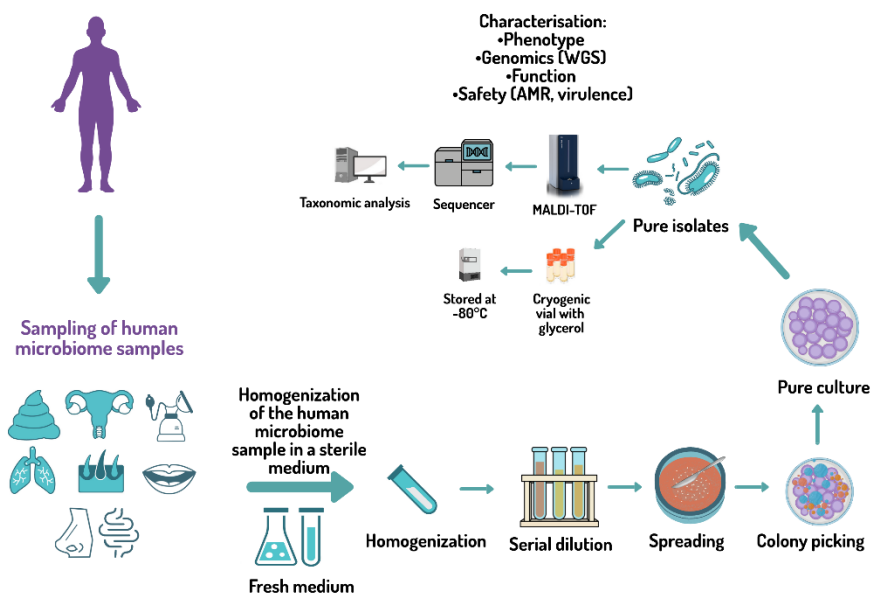


Figure 1. Illustration of the isolation process of pure strains from human microbiome samples.

Unlike microbiota sample, isolated strains are clonal cultures derived from a single cell. This is different from microbiota samples, which generally contain an “unknown” fraction, such as additional microorganisms and/or human-derived cells or substances (human DNA, metabolites,...). As a result, these isolated strains are fully identified (typically through whole-genome sequencing and phenotypic characterization), extensively characterized, and demonstrated to be pure and clonal, as a direct consequence of the isolation process.

Once isolated, pure strains are stored in dedicated strain banks, either private collections or recognized public culture collections (e.g. ATCC, DSMZ, BCCM, CNCM), ensuring traceability, long-term stability, and controlled access.

### 1.2. Isolation of pure microbial strain from human microbiome samples constitutes **comprehensive risk mitigation measures**.

For the sake of clarity, we also would like to explain certain aspects related to the **activity of isolating strains**, in order to avoid any confusion with the activity and definition of **faecal microbiota transplantation (FMT)**.

The isolation process is a microbiological process, in which single cells of a micro-organism are isolated on multiple occasions through culturing steps to ensure purity, followed by an expansion of the micro-organisms for the process of cell banking and manufacturing. These are clonal products, originating from a single parent cell, with all

subsequent cells being genetically identical "clones," of that original cell. The original isolated cell is no longer present in cell banks or manufactured products. In fact, none of the original SoHO material remains after clonal isolation and cell expansion. This is very distinct from isolation based solely upon physical separation, for example the physical separation of a population of microbial cells from e.g. human cells and/or human-derived substances

The purpose of the isolation of a strain is the selection of a **single microbial cell**, its isolation and characterisation, followed by controlled multiplication through fermentation, its subsequent processing, packaging, and distribution. This activity complies with applicable safety and quality requirements, for placement on the market as an industrially manufactured product.

This activity differs fundamentally from microbiota transplantation (such as fecal microbiota transplantation or vaginal microbiota transplantation), which involves the administration of a **complex and non-defined microbial community** from donor. The two activities differ fundamentally in terms of **nature, degree of characterisation, risk profile, and regulatory context**.

**1.3. Human microbiota samples (including, but not limited to, gut, skin, vaginal, and lung microbiota samples) may be collected and used for the purpose of isolating microbial strains (e.g. bacteria, yeasts, viruses).**

It is important to stress that, at the time of collection of microbiota samples and initial isolation of strain(s), the intended downstream use of an isolate is generally not known. Isolated microbial strains (bacteria, yeasts, viruses, etc.) may subsequently be used in the manufacture of a wide range of finished products, including medicinal products, medical devices, foods, food supplements, foods for special medical purposes (FSMPs), cosmetics, and other applications (Figure 2 – use of isolated strains used for several applications).

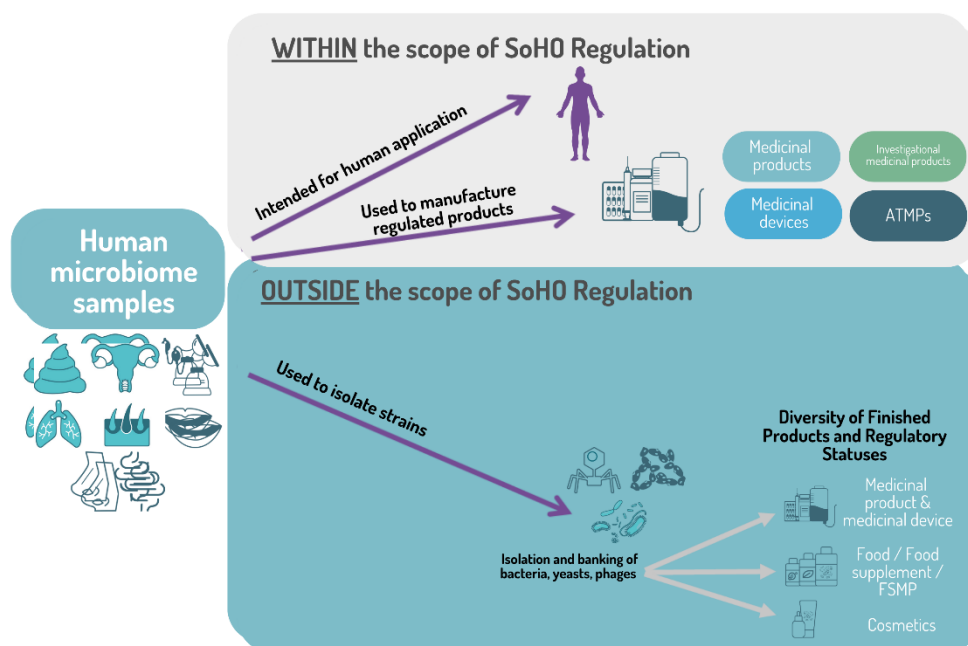


Figure 2. Illustration of the intended uses of human microbiome samples that fall within the scope of the SoHO Regulation—namely, applications involving direct human use (e.g. FMT or VMT) or the manufacture of regulated products such as intestinal microbiome whole-ecosystem-based medicinal products. In contrast, the use of human microbiome samples solely for the isolation of strains does not fall within the scope of the SoHO Regulation. The illustration further highlights that such isolated strains may subsequently be used to manufacture a wide range of finished products, including medicinal products, medical devices, foods, food supplements, foods for special medical purposes (FSMPs), cosmetics, and other applications.

Any subsequent application involving human use and human application of these strains would only occur after extensive steps, including full characterisation, safety assessment, and compliance with the relevant regulatory framework linked to the intended use of these strains. As such, no direct risk to human health is associated at the stage of isolation and banking. However, we fully recognize that there is a need to protect SoHO donors, and the principles of voluntary and unpaid donation as well as consent would also apply, in order to protect all donors, whatever the fate of their samples.

Based on the above, we consider that isolation of strains is not a SoHO activity as per Art 2.1(c), meaning that organizations performing strain isolation should not be considered as SoHO entity nor SoHO establishment. This point has already been raised in the context of the public consultation and referenced in the comments submitted during the EC consultation<sup>1</sup>.

<sup>1</sup> EC Public Consultation [Feedback from IPA Europe - Probiotic Europe](#); [Feedback from Pharmabiotic Research Institute \(PRI\)](#)

### 3. Rationale supporting the Exclusion of Isolated Strains from the SoHO Scope

Isolated strains are outside the scope of the SoHO regulation as “isolated strains” are different from “microbiota”, and the risk associated with isolated strains is significantly reduced by the isolation process, banking system and manufacturing process of the various finished products for which these strains are used. Furthermore, all finished products containing strain(s) isolated from human origin are covered by dedicated regulatory frameworks setting up the requirements and standards to place the products on the European market. All finished products incorporating such strains must comply with stringent safety, and quality requirements prior to market authorization.

In fact, the risks associated with the use of isolated microbial strains in manufacture of products are already comprehensively addressed through existing EU regulatory frameworks, depending on the intended use of the final product containing these strains, such as:

- Pharmaceutical legislation (including live biotherapeutic products) (Directive 2001/83/EC and Eur. Ph. Monograph 3053)
- Food law (including General Food Law - Regulation (EC) No 178/2002 and Novel Food Regulation - Regulation (EU) 2015/2283)
- Cosmetics legislation (Regulation (EC) No 1223/2009)

Under the general EU food law, foods placed on the market must be safe and fit for human consumption. These fundamental principles are already embedded in the existing EU regulatory framework. Notably, under the Novel Food Regulation, the European Food Safety Authority (EFSA) conducts safety assessments of microorganisms that do not have a history of safe use prior to their authorisation on the EU market. This Novel Food procedure also concerns strain isolated from human microbiome samples, without an history of human consumption as it is the case of at least 2 dossiers recently evaluated by EFSA (pasteurized form of *Akkermansia muciniphila*, authorized for use in foods for special medical purposes and food supplements<sup>2,3</sup> ; *Anaerobutyricum soehngenii* CH106 (ongoing risk assessment<sup>4</sup>).

In addition, the Qualified Presumption of Safety (QPS) approach, established by EFSA in 2003, provides a harmonised and science-based methodology for the safety assessment of microorganisms, supporting regulatory consistency across applications.

Similarly, the use of single microbial strains in humans as Live Biotherapeutic Products (LBPs) is already addressed through medicinal product legislation, which imposes

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<sup>2</sup> EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) et al. Safety of pasteurised *Akkermansia muciniphila* as a novel food pursuant to Regulation (EU) 2015/2283. EFSA J. 19, e06780 (2021).

<sup>3</sup> The European Commission. Commission Implementing Regulation (EU) 2022/168 of 8 February 2022 Authorising the Placing on the Market of Pasteurised *Akkermansia Muciniphila* as a Novel Food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and Amending Commission Implementing Regulation (EU) 2017/2470. (2022).

<sup>4</sup> Seegers, J. F. M. L. et al. Toxicological safety evaluation of live *Anaerobutyricum soehngenii* strain CH106. J. Appl. Toxicol. JAT 42, 244–257 (2022).

stringent quality, safety, and efficacy requirements for all medicinal products, including the one containing live microorganisms (bacteria or yeasts) for human use (LBPs and microbiome-based medicinal products). The use of these strains in medicinal products is covered by the Eur. Ph. Monograph 3053 (Live biotherapeutic products for human use)

This is different from certain SoHO (e.g. human breast milk) intended for ingestion, which remain regulated under the SoHO framework due to their intrinsic nature as substances of human origin.

While the point regarding “SoHO used for ingestion” was already included in the AQID3 point from the Compendium of Questions & Answers published by the SCB, it does not clarify the status of isolated strain from human microbiome samples.

The specific case of **isolation of microbial strains from human microbiota samples** introduces a potential area of ambiguity and confusion at the interface of regulatory frameworks. Addressing this ambiguity is the purpose of this joint position. PRI and IPAEU stress the need to avoid unintended impacts of the SoHO Regulation on innovation related to microbial strain isolation as strain isolation is an early-stage activity that underpins innovation across multiple regulated sectors.

## Conclusion

In light of the above considerations, PRI and IPA Europe conclude that:

- Microorganisms isolated from human microbiome samples are not considered as SoHO or SoHO preparation, and therefore should be considered outside the scope of the new SoHO regulation (Regulation (EU) 2024/1938).
- Isolation of strains is not a SoHO activity as per Art 2.1(c), meaning that organizations performing strain isolation are not considered as SoHO entity nor SoHO establishment.
- The subsequent use of these microorganisms is already regulated under appropriate sector-specific legislative frameworks ensuring the high standard of safety required by the EU.

PRI and IPA Europe stress the need to avoid unintended consequences of the SoHO Regulation on innovation related to microbial strain isolation, as this activity underpins innovation across multiple regulated sectors and may have significant implications for European industry and a broad range of products across medicinal products, medical devices, foods, food supplements, foods for special medical purposes (FSMPs) and cosmetics.

**Conclusion:** In order to support a harmonised interpretation, implementation and application of the SoHO framework, the Associations propose that this topic should be

included in the agenda of a forthcoming SCB meeting. We would welcome the opportunity to present and discuss this position.

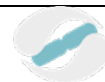
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IPA Europe is the European association representing leading producers of probiotic cultures, probiotic foods and food supplements, as well as nutritional and therapeutic products. We promote the probiotic category in Europe by providing scientific and regulatory expertise, and fostering collaboration across science, industry, and policy stakeholders. With IPA, the International pre-, pro-, and post biotic association, we bring together a unique forum of about 120 companies worldwide.



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PRI is the largest microbiome network in Europe, representing over 70 members across industry and academia engaged in microbiome innovation. As a recognised stakeholder at European level, PRI actively engages with regulatory authorities and policy makers. It brings together a broad and representative voice of the microbiome sector to support the advancement of microbiome innovation.