

## PRESS RELEASE

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**IPA Europe contends that scientists and clinical researchers – both academic and from industry – as well as journalists must remain diligent in their assessment of research results. A quantitative and qualitative comparison based on only 8 subjects is, from a scientific viewpoint, not considered particularly reliable and certainly does not allow for sweeping conclusions on probiotics in general.**

A recent study<sup>1</sup> which has received media coverage is questioning the health benefits of probiotics. The conclusion of the authors that probiotics seem to be delaying the recovery of the microbiota is in stark contrast to one of the most accepted observations, namely that probiotics limit the side effects that can be expected during or after antibiotic intake. Placebo-controlled clinical studies have confirmed this clinical outcome for a very large variety of probiotic preparations. In this perspective, it is important to note that the investigators used a probiotic combination that does not seem to have any clinical documentation and is poorly defined. As the authors provided no explanation for the observed ‘delay in the recovery of the microbiota’, we propose this is investigated further before drawing firm conclusions.

IPA Europe contends that the studies referenced basically confirm the knowledge that we already have on probiotics: namely that probiotic strains are indeed likely to have individual responses; if you already have a high level of bifidobacteria in your gut, a bifidobacterial supplement will not add a lot, for people that are low in bifidobacteria the supplement may indeed help.

It is regrettable that, although the authors themselves state that the microbiota is influenced by very many factors and is extremely diverse, their ‘study group’ consists of only 8 people, which in our view is too small to be able to reliably evaluate so many parameters or to draw any far-reaching conclusions.

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<sup>1</sup> i.e. by Zmora, et al. "Personalized gut mucosal colonization resistance to empiric probiotics is associated with unique host and microbiome features" and Suez, et al.: "Post-antibiotic gut mucosal microbiome reconstitution is impaired by probiotics and improved by autologous FMT"

Regarding the content, it is important to realize that probiotics should not colonize but should establish themselves only transiently. This is a basic safety requirement for probiotics and the FDA will categorically refuse any probiotic that shows permanent colonization.

Concerning the methodology, it is obvious that an autologous faecal transplant (*your own stool being taken before an intervention*) is more effective than a probiotic strain in restoring a disturbed microbiota, however, faecal transplants are not very likely to become a routine intervention for the total population. Indeed, the safety of this procedure is the subject of considerable debate; the FDA requires physicians and scientists to file an Investigational New Drug (IND) application if they intend to use the treatment for clinical practice or research<sup>2</sup>.

**To conclude, IPA Europe scientific experts consider that the observed effect could perhaps be linked to the probiotic mixture used or to the readout of the test, which is not a clinical outcome, but a complex microbiota analysis, prone to, as argued above, an extreme diversity and variability due to numerous environmental factors. A quantitative and qualitative comparison based on only 8 subjects is, from a scientific viewpoint, not considered particularly reliable and certainly does not allow for sweeping conclusions on probiotics in general.**

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#### ABOUT IPA EUROPE

IPA Europe is the European chapter of IPA, the International Probiotics Association; it was established in Brussels in 2015. The members of IPA Europe are companies directly engaged in the manufacture of probiotic cultures or probiotic foods, supplements, nutritionals or therapeutic products: BioGaia, Chr. Hansen, Danone, DuPont, IPA, Lallemand, Lesaffre, Probi and Yakult. The IPA Europe mission is: to gain acceptance of the term “probiotic” throughout Europe as a defined category and to create a favourable environment for probiotics in Europe. For additional information on IPA Europe’s activities see: <http://ipaeurope.org>

#### FOR MORE INFORMATION

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<sup>2</sup> A How to Guide: Investigational New Drug Application for Fecal Microbiota Transplantation  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947095/>