

Probiotic era

How do you balance risk and opportunity in microbiome-based innovation? Ankita Singal-Sareen, R&D strategy & innovation key account management, Sagentia Innovation explains



The global market for pre- and probiotic products continues to grow at pace, and the opportunity to personalise such products could unlock further growth for food and beverage companies – but what are the options, how are they best realised, and what risks are involved?

Personalised products that improve individual health and wellness show much promise. However, the gut microbiome is still an emerging field. There is no single definition of a ‘healthy’ gut microbiome or of an ‘unbalanced’ microbiome (dysbiosis). What’s more, microbiome data is not an established biomarker. So, while the potential is great – and continues to grow – aligning microbiome-based food and beverage personalisation with robust scientific evidence is not straightforward.

Much of the scientific rigour stems from investigation of multiple microbiome-disease associations like coronary artery disease and inflammatory bowel disease. Another area of significant activity is the gut-brain axis. Some studies indicate a causal effect between gut microbiota, the brain and behaviour, giving rise to ‘psychobiotics’ which might offer mental health benefits. Postbiotics, para-probiotics and synbiotics are also attracting attention.

Evidencing causal links between diet, gut microbiome health, and wider health and well-being is complex, and it’s just part of the equation. Developments must also walk a fine line between risk and reward in commercial, technical and regulatory matters.

Commercialising microbiome-based innovation

Commercial models for microbiome-based food and beverage personalisation require careful consideration. At present, a truly individualised approach is unlikely to be cost-effective at scale in most scenarios.

A potential starting point for commercialisation could involve consumer segmentation and stratification to underpin mass personalisation. This makes the benefits of personalisation accessible in an economically viable way. Propositions could be aimed at specific population cohorts or ‘need states’ based on factors like lifestyle, demographics and health conditions. For instance, mass-customised microbiome-based products and services geared towards pre-diabetics or the elderly could have great potential. Gut-brain axis as an innovation space is also fast evolving, as science joins the dots. Probiotic solutions which address depressive mood, anger and fatigue, and to improve sleep quality, are being commercialised (eg Bifivir – Probiotical, Italy).

Right now, global corporations are investing in propositions to drive better substantiation of evidence. Last year, Seres Therapeutics and Nestlé Health Science announced a co-commercialisation license agreement for SER-109, an oral investigational microbiome therapeutic for recurrent *C. difficile* infection.

In terms of business models, several companies provide microbiome analysis and advice based on the results. However, some go a step further to offer personalised supplements such as precision prebiotic and probiotic mixes. These include Viome, which acquired Habit from Campbell's Soup Company, and has a vision for a 'whole body' approach to human health.

Technical considerations

An important factor in microbiome-based personalisation is the manufacture and distribution of products.

Installed manufacturing footprints of most food and beverage companies are designed with scale and convenience in mind. However, mass production can conflict with a personalised approach. Difficulties vary between different environments and product types, so there is no single solution. Challenges associated with packaged foods (eg product stability) are quite different to those in the food service industry where products are prepared for immediate consumption. Further innovation is needed in the encapsulation of probiotics to increase viability and controlled release in the gut.

Another area bubbling under the surface is precision engineering of the microbiome (e.g. Eligo Biosciences). This technology is currently only relevant to the pharmaceutical industry, however it will be interesting to watch its evolution and impact on the increasingly blurring interface between functional foods and consumer healthcare.

Food and beverage companies aiming to lead microbiome-based innovation will need to devise innovative 'product plus service' models for health and wellbeing which offer diagnostics and longer-term assessment. The level of sophistication could vary greatly, ranging from simple online questionnaires and app-based regimes to provision of stool samples for detailed microbiota analysis. Either way, this will involve direct interfaces with consumers which need to be carefully constructed and managed, bringing additional technical complexity.

Regulatory challenges

When innovating microbiome-based products and services that may offer health and wellness benefits, upfront awareness of regulatory



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challenges can de-risk investment. Questions should be raised about the survivability of microorganisms within final end-products, their physiological manifestations and their benefits. These affect the validity of health and marketing claims, which can be a powerful communication tool to appeal to consumers.

Currently within EU and UK markets there are no approved health claims in relation to use of probiotics. Approximately 90 submissions have been made to the European Food Safety Authority (EFSA). All were deemed non-authorised because the relationship between the substance and the health benefit is not substantially validated. Manufacturers ought to carefully consider this when submitting a dossier for pre-market approval.

On the other hand, marketing claims may be used with caution. These must be truthful, not ambiguous or misleading, and properly substantiated.

Lastly, with food and beverage manufacturers focused on creating microbiome-based products with a potentially therapeutic effect, it should be noted that products cannot carry claims such as 'cure', 'prevent' or 'treat'. Such products would be classified as medicines, and subject to medicine regulations.

As it stands, microbiome-based food and beverage innovation offers exciting possibilities for the future. However, it must contend with tight scientific and regulatory boundaries, as well as technical and commercial challenges. Alongside this, consumer demand presents risks as well as opportunities. Expectations are high, and may be out of kilter with the science. Nevertheless, companies tackling the difficult questions now will be well placed to deliver effective microbiome-based products that support individual health and wellness [\[7\]](#)