Thank you for your letter dated 27 February 2019 to Richard Harrington concerning microbiome research and applications, and for highlighting some of the issues raised by Dr Chris Brown from the Society of Applied during the 'My Science Inquiry' in January. I am responding as the Minister for Science. Following discussions with officials in the Department for Health and Social Care, and the Department for Environment, Food and Rural Affairs, I have addressed each of the points raised in your letter below.

**Research in some areas on the application of microbiomes being more developed than others**

UK Research and Innovation (UKRI) investments in microbiome research span a wide range of contexts, including humans, animals, agriculture, and the natural environment. UKRI support encompasses funding for basic science through to more applied and translational research areas, as well as investment in relevant infrastructure and skills. There are strong relationships between microbiome research and broader UKRI investments in fundamental and applied microbiology, as well as key challenge areas including tackling antimicrobial resistance, food nutrition and health, sustainable intensification of agriculture, and combating climate change.

UKRI investment in Microbiome research is primarily through the Biotechnology and Biological Sciences Research Council (BBSRC), the Medical Research Council (MRC), the Natural Environment Research Council, and Innovate UK. At the time of this letter these currently invest £69m in 118 projects on microbiome research.
In addition, BBSRC with regional partners has invested £75m in Norwich at the recently opened Quadram Institute, which is a key centre for understanding how food and the gut microbiota are linked to the promotion of health. Quadram has a major programme to understand what constitutes a ‘healthy’ microbiome and has also been developing approaches to microbiome therapies, particularly against the important human pathogen *Clostridium difficile*.

Other examples of specific UKRI investments relevant to microbiome research include:

- **EBI Metagenomics** platform: an internationally-leading resource for the analysis and sharing of microbiome research data (BBSRC)
- **CLIMB**: an infrastructure providing cloud-based computing platform to enable analysis of microbial bioinformatics and metagenomics data (MRC)

In addition, the Department of Health and Social Care funds research through the National Institute for Health Research (NIHR). The NIHR welcomes funding applications for research into any aspect of human health, including on the microbiome/microbiota. For both UKRI and NIHR it is not usual practice to ring-fence funds for particular topics or conditions. Applications are subject to peer review and judged in open competition, with awards being made on the basis of the importance of the topic to patients and health and care services, value for money and scientific quality. The NIHR has directly funded and supported research studies on the microbiota and microbiome totalling £23.8m in since 2011/12.

**Regulation**

- **Products developed for use in healthcare and agriculture facing regulations meant for the chemical and pharmaceutical industries**
- **Consumer regulation** – ‘at home’ test kits available for anyone to test their gut microbiome despite the link between microbiomes and certain diseases in some cases being unclear

**Health**

There are no specific regulatory processes identified currently for the use of microbiomes. There is uncertainty of the link with diseases and the benefit of intervention in altering the microbiome. If these were considered medicinal products, then the same regulatory provisions will apply including evidence generation from clinical trials. There have been no products thus far and so regulatory experience is limited. The Medical and Healthcare products Regulatory Agency (MHRA) have approved two clinical trials for Faecal Microbiota Transplant (FMT) as a medicine and advised on the manufacturing and trial submission requirements with the sponsors.

**Agriculture**

The EU regulatory regime has specific data requirements and guidance for agricultural microbiological active substances and products.

**DNA home test kits/companies offering microbiome testing**

While some tests are being proposed, the benefit of testing of microbiome DNA is still unclear in specific disease states. The MHRA would encourage developers to engage early with MHRA’s innovation office. This acts as a single point of access to free and expert regulatory information, advice and guidance that helps organisations of all backgrounds and sizes, including SMEs and individuals to develop innovative medicines, medical devices or novel manufacturing processes.
This service helps to make regulatory information clear and accessible to those who are working on innovative projects, ensuring that the UK remains one of the best places in the world to develop life sciences projects, in order to protect health and improve lives, here and around the globe.

More widely, the Consumer Protection from Unfair Trading Regulations 2008 (CPRs) prohibit traders from engaging in unfair commercial practices (mainly marketing and selling) against consumers. Under the CPRs, traders must provide consumers with the information they need to make informed purchasing decisions. The Regulations prohibit unfair commercial practices, which omit or hide material information, which the average consumer needs, according to the context to make an informed choice.

Some countries (such as the US) being ahead of the UK in this area – in 2016 the US govt invested $120m into the launch of a National Microbiome Initiative. At the same time, more than 100 external organisations announced over $400m in financial and in-kind contributions in support of the overarching goals of the US govt’s initiative. The US govt also created a working group to devise a cross-govt strategic plan for microbiome research, which was published in April 2018.

The UK is already benefitting from its world class bioscience base working across industrial sectors and bringing together government, businesses and the research community. “Growing the Bioeconomy: a national strategy to 2030” published in December 2018 will ensure that the UK becomes an inviting and vibrant place to invest and do business, supporting innovation and economic growth.

It is difficult to generalise the stage of advancement of microbiome research, both in the UK and globally, owing to the diversity of research areas covered. What is true for human microbiome studies will not necessarily correspond for crop microbiomes, for example. It is apparent that the majority of investment internationally has been in the human microbiome area, and this is probably also more developed from a translational perspective. Despite this, many studies to date have focused on microbiome DNA sequencing and have drawn correlations between microbiome and health status without providing a robust explanation for cause and effect. There remain many outstanding questions about the true role, function and impact of complex microbial communities, and a need to support high-quality fundamental research to address these questions if microbiome science is to be credible and have a major impact. Supporting exploitation of research findings to practical end use and/or commercial exploitation remains a key goal for UKRI.

Whether the Govt is considering introducing a specific national microbiome roadmap

Government’s views on whether such a roadmap could help to identify the key opportunities for growth and ways to coordinate funding, accelerate innovation and stimulate the early adoption of technology

If the Govt has investigated microbiome research as a route to help deliver the goals stated in its Strategic Vision for the UK bioeconomy in 2030

The development of a microbiome roadmap would support the aims of our Bioeconomy Strategy, especially the ambition to develop our strengths in research, development and innovation capability and to make best use of natural resources. However, any plans for a coordinated ‘national roadmap’ for microbiome research. would need to fully consider the
diversity of research application areas within this area. Within UKRI, the relevant funders meet regularly to discuss the area and ensure their activities are coordinated wherever possible.

There is a need to recognise that microbiome research cuts across a range of sectors and a 'one size fits all' approach is unlikely to succeed. There would be benefits to enhanced networking across research domains with interests in cross-cutting microbiome areas such as data analysis, tools and methods, regulatory issues, engagement between academia/industry/end users.

CHRIS SKIDMORE MP