The Evolution of Personalised Nutrition: Conclusions

Summary of the personalised nutrition landscape

Personalised nutrition in its current implementations has had a slow evolution so far for well over two decades. Although largely convincing in clinical settings, the underlying science base of PN and related software technologies still need to improve significantly in a commercial consumer context. Providers on the market are still developing and testing commercially viable business models to be able to offer trustworthy and scientifically valid services at an affordable price. The number of providers of genomics based PN is small globally (around 50, with around 15 in the UK), and served markets are still mostly curiosity customers who make one-off purchases or subscribe for a few months. The PN providers offering a personalised food product are doing so either in the form of personalised vitamin formulations or supplement mixtures to be consumed as meal shakes or snack bars/cookies, which are regulated by the UK food law. Consequently, these businesses need to be registered as a Food Business Operator (FBO).

Despite its slow evolution as a separate offering outside of traditional healthcare, growth might accelerate in the longer-term future through network effects with other recent trends in the food sector, and food related regulation might then begin to play more of a role. One of these trends is general food customisation via software enabled means to personalise meals, food shopping, and cooking, or via food processing technologies, such as 3D printing, and local small to medium-scale speciality food producers catering to niche markets.

Once the science base of PN becomes more robust and trusted by consumers, ecosystem effects such as partnering between food producers and PN service providers would enable a seamless personalised food service in which the PN providers inform consumers what food and how they should consume their food, and food producers might be technically equipped to provide actual personalised food products to match that advice. Proponents envisage a world of restaurants providing customised menus, personalised meal delivery services, and mass-customisation. However, this is currently still speculative as the existing food system is built to provide standardised mass-produced food at affordable prices, which runs counter the idea of producing individualised food items with limited editions. However, should small to medium scale food production processes become viable locally then personalisation might become a specialist production mode for such food processors that could link up with PN service providers and create submarkets for personalised food items.

Implications and recommendations for FSA

The current PN market in the UK is still limited and most active companies are at an early stage in their development, mainly small start-ups in their first or second funding round having raised a few £100,000 to a few million pounds, mainly in the past five years. However, 9 out of 13 surveyed active companies in the UK offer personalised vitamins or supplements, which may indicate that this is the direction into which PN providers will be going in the medium-term future

(see Appendix A). As PN is still a curiosity market with mostly one-off purchases or subscriptions for a few months the total market coverage of these UK companies at any given time may currently be in the range of thousands up to the lower hundreds of thousands of customers, based on their self-reported customer figures, with a potential temporary peak during the height of the Covid-19 pandemic during which consumers tended to seek out heath improvement offerings.

With regards to FSA regulatory remit two aspects of PN services might be of relevance for considerations to what extent FSA might be able to contribute in a positive manner to the development of the sector. First, given existing FSA leverage in the supplements and vitamin sector and therefore also their labelling within a PN context, it might be straightforward to achieve regulatory impact by making sure that personalised products are not labelled and presented as a medicine. Second, enforcing registration as a food business when selling supplements might also help PN businesses understand that the health claims made in their personalised advice based on biomarker and DNA data may not be translated into health claims on their supplements. For the food and labelling regulators (including the FSA, Department of Health and Social Care, DEFRA) to take a clear stance on food related health claims in general might also help with generating a more trustworthy business culture that will help build consumer trust in the sector. The specifics of how PN offerings are presented, and which services and products are sold depends on the individual business model of each company, hence the degree to which their activities fall within the FSA's remit might need to be assessed on a case-by-case basis.

Summary of emerging personalised nutrition approaches and implications for FSA

Based on the definition of personalised nutrition given in this report (section 2.1) a number of business models can be found implemented by currently active PN providers. In addition, there are other on-going activities in the food sector that can be called "personalisation of food", which are different from personalised nutrition as discussed in this report. Personalisation of food services range from shopping platforms tailored to specific dietary needs/preferences, such as for vegans, vegetarians or food intolerant consumers, to personalised dining experiences in restaurants, or personalised modes of production of certain foods, for example via 3D printing among others. Although these activities within the food sector are potentially relevant in the future for enabling an ecosystem of interlinked customisation/personalisation technologies that might connect in the longer-term future with PN providers in the stricter sense to provide integrated services, these are not discussed here as they are already within FSA remit. The following types of PN services currently implemented on the market have different implications for consumers and FSA regulatory remit.

1. **Services based only on personal data on phenotype, lifestyle dietary habits, and physical activity patterns etc**. Currently not within FSA remit as it is advice only that can be seen equivalent to general advice by nutritionists and dieticians.
2. **Services based on personal data and bio-specimen test results** (including from blood, saliva, stool, breath, and sweat among others, but excluding personal DNA). Here the FSA may wish to consider taking on responsibilities at the intersection between health claims on foods or supplements that are made with an understanding of addressing specific health issues identified by personal phenotype data using scientific methods. There could be an opportunity for setting standards for a certain level of required scientific validity and robustness of test results before health claims on advised foods can be made. A stricter regulation of claims concerning this relationship between personal health requirements and food claims might be justified on the basis that this relationship is presumed to be specific to the customer receiving personalised nutrition advice, and hence can be different to claims that have their origins in large population studies. A clearer language in this respect may help with building a framework of trust between providers, consumers and regulators.

3. **Services based on personal DNA sample test results and analysis**. As in B, FSA may wish to take a stronger position at the interface between claims on food and the scientific justifications for the effectiveness of certain foods in addressing health issues identified through DNA analysis in individual customers.
4. **Services based on any of, or, a combination of A-C, and offering a food product such as supplements, functional foods, or vitamins**. This segment already falls within FSA remit, however as discussed in section 7 it is currently unclear whether the PN sector has sufficient awareness of existing regulation, and it certainly appears that claims are made that are questionable with regards to vitamins and supplements sold in combination with personalised advice based on individual scientific results and analysis. In particular, the distinction between food and medicine needs to be upheld by making sure that the presentation of sold food items such as supplements does not blur that line deliberately, and that all other relevant regulation for supplements is adhered to, including food safety aspects, labelling, allergen advice etc. to avoid consumers being misled to believe that supplements offered by a PN provider are qualitatively different from other supplements.

General recommendations for consideration

Given that business models in the sector currently vary and whether the PN provider would sell personalised supplements and functional foods, FSA may wish to make a decision whether it would be appropriate to develop a broader framework that would cover any PN companies, or just the ones that would also provide supplements and functional/personalised food items or vitamins.

Although explicit regulation of all PN providers may currently not fall directly under FSA remit it is advisable that FSA directly collaborates with medical regulatory agencies in drawing up a framework of understanding for necessary regulation to ensure general quality standards in the PN sector can be enforced effectively. This includes collaborating with relevant organisations that cover the data aspect of the sector to such as validation criteria for biospecimen and DNA testing, algorithm standards and data ownership and privacy rules. Harmonising the regulatory framework for PN across agencies will enable the industry to evolve in line with consumer protection across the service offering. In such an effort decision on the following areas need to be made in collaboration with other regulatory bodies:

- Analytical validity of tests: requiring analytical tests to be carried out by certified laboratories in the UK. In case of test samples being sent to other countries due to perceived or real economic advantages, the overseas laboratories need to comply with UK validation standards in order to be able to process samples from UK consumers.
- Scientific validity of analysis: science in this field is still evolving and new findings are emerging that may impact the nature of analysis of data and how the algorithms used by PN providers are designed. This in turn will impact the nature of advice given to certain individuals or subpopulations. Therefore, it would be advisable that regulation would require PN companies to update their algorithms based on the latest relevant scientific findings.
    - For the FSA and other regulatory bodies working on this issue it would be advisable to aim for harmonisation of validation requirements for algorithm certifications with highest clinical standards. This can be addressed by working with a science advisory board to be able to 1) keep up with the latest scientific breakthroughs 2) translate the latest scientific findings into validation parameters that need to be considered for algorithm certifications.

This is important, because the advice PN companies offer is not based on human judgement but rather is the result of a chain of software automated decisions that underpin the AI that is used for final advice given. In cases of automated advice causing harm to consumers the question of legal responsibility needs to be traceable to the technologies involved. Therefore, the parameters that the algorithms are trained on need to be accessible for external validation and need to reflect

latest scientific findings as the field progresses.

- Utility of advice: considering that at the current state of the industry the algorithms that underpin automated advice are trained and built upon the individual knowledge and experience of dietician/s or scientists working with each start-up. Therefore, the previous point on scientific guidelines on validation parameters of algorithms will be a key point for harmonising rules that are being used to train algorithms.
    - At the same time as the PN sector grows and increases its customer base to the millions, feedback and data regarding how different individuals responded to these new dietary interventions and their impact on their health outcomes, will become a very valuable source of empirical data for research. Owning this data can become a monetisable and valuable source of competitive advantage depending on how this information is used.
- Ethical, legal and data protection issues need to be covered by collaborating with relevant regulatory agencies.

Short-term FSA priorities (within 3 years)

- Establish within the FSA whether a more active role in regulating businesses that are operating at the intersection between health/wellness and the food system would be desirable for protecting consumers from low quality services linked to food, or outright fraud. This may involve changing existing remit definitions. In terms of the early developmental stage of the industry this could be an opportunity to shape its further evolution.
    - Build the necessary collaborations with other regulatory agencies that have responsibility for different areas of this multidisciplinary space.
- Ensure that the FSA has the relevant expertise required for monitoring the emerging PN sector by connecting with relevant experts. This will require maintaining networks of experts in the basic sciences who understand relevant scientific trends that may lead to applications relevant for the PN sector. Other additional expertise required would be:
    - Experts from the social sciences to provide insights into other societal trends that may be relevant for this sector.
    - AI, privacy, and data security experts to provide a deeper understanding of how science is translated into advice and its implications for personal privacy of consumers.
- Monitor activities and connect with experts in the areas of general food personalisation, in particular where synergies with the PN sector could lead to a sudden market growth of PN services due to production capacities that may become available from different segments of the food processing sector. This is advisable as already a number of large multinational food producers are supporting the PN sector via partnerships and start-up funding.
- Explore whether existing regulation of supplements and vitamins is adequately covering the various aspects of PN services and whether a closer analysis of the sector would be required to establish to what extent existing regulation is adhered to.

Medium-term FSA priorities (3 to 5 years)

- Consider whether the FSA might be a relevant partner in potential efforts to make PN services available to larger segments of society with public health goals in mind. This may involve connecting with the NHS and the Department of Health and Social Care to explore to what extent such efforts are realistic.
- Consider establishing strategic partnerships with the public health, healthcare and social services regulatory bodies in order to bring food safety aspects to health regulation relevant for the PN sector.

Long-term FSA priorities (5 to 10+ years)

- It remains crucial to closely monitor the sector's evolution as novel science results from areas such as epigenetics, gut microbiome, metabolism research among others, will come to market, again at an early stage of understanding, potentially claiming to be more valid than current applications.
- Explore to what extent a growing PN market might impact the way how consumers interact with the wider food system in a networked fashion, how such network effects might be utilised for achieving public health goals, and whether as a food regulator there would be opportunities for supporting such goals.

Limitations of study

This report is believed to have captured the most salient science, technologies, services and trends immediately relevant to the evolution of the PN sector. As PN is a fairly well researched and studied subject in its own right we believe the most relevant findings from the academic and grey literature in the public domain are captured in this report. However, for giving a more detailed account of the current impact of PN providers on consumers, a more detailed analysis of the currently active commercial players would be required. More in-depth commercial information is however often not available either due to the short period of commercial activity of companies, or not made available due to issues around IP or confidentiality. Though care was taken to report on most relevant trends impacting the evolution of PN, no attempt was made to quantify them in terms of size of potential impact, as this would have required additional research and methods beyond the scope of this report.

Recommendations for future research and analysis

- To get a clearer understanding of the current state of adherence to existing legislation in the PN sector a study should be carried out to establish such information from existing providers.
- For anticipating synergistic effects between PN and existing "personalisation of food" activities in the food processing industry, a study of currently existing food personalisation technologies and trends within this segment should be conducted.