

How do you choose a Good Probiotic?



Aileen Green BSc (Hons) MPhil

Research, Development and Quality Director, Probiotics International Ltd.

With the explosion of many probiotic products on the market over the last few years, how do you know which one to choose? Which will work? How can you guarantee the quality of the product you are buying or prescribing? The information provided in this article will help you decide which products to use.

Strain Selection, Fermentation, Microencapsulation & Freeze Drying

Probiotic strains need to be carefully chosen. Survival through the stomach (and capability to resist gastric juices) as well as survival under normal storage conditions are important factors to be considered. If the strain is not resistant to gastric juices, it is unlikely to reach the area of influence in the gastrointestinal (GI) tract.

Fermentation of probiotic bacteria is a very specialised process that involves high tech machinery and highly qualified personnel – there are only a few companies in the world who can successfully carry this out.

The process starts with the 'mother strain' being added to culture media of increasing volume specific to that strain and transferred to a fermentation chamber for full scale production.

The fermented media is then filtrated a number of times to discard the culture media and leave just the bacteria. The concentrated bacteria are then mixed with a cyroprotectant (microencapsulation) which further enhances protection of the bacteria through the stomach as well as protecting the bacteria during the freeze drying process.

The filtrated bacteria in a liquid form is then almost instantly frozen to -40°C almost instantly to enhance the shelf life of

the bacteria. In this specialist process the ice crystals are then converted to steam to leave a solid crust ready to be ground.

Packaging

Probiotics are very susceptible to moisture and fluctuating temperatures. Therefore, packaging of the product to afford the most protection as possible from the environment is of great importance. Exposure to these factors can have a detrimental effect on the shelf life of the finished product and therefore effectiveness. Reducing this exposure during the manufacturing and packaging of products is of great importance.

Quality Assurance

When manufacturing probiotic products, high quality standards and processes are imperative. This ensures that the product is manufactured to the highest standard to result in a product that not only meets label specification but is also effective and safe to use.

GMP (Good Manufacturing Practice), ISO 9001:2008 (International Standard for Quality Management Systems), and HACCP (Hazard and Critical Control Points) analysis are accreditations that show a product is manufactured to a high standard.



In addition to this, the product should be tested by an independent, fully accredited laboratory (lab) which has the expertise to enumerate (count) the probiotic strains. Quality assurance should rank highly on the priority list for each company and full traceability should be as standard.

Safety

There are three main questions to consider with regards to the safety of probiotic products:

- Does the product contain the type of microbes it claims?
- Do the probiotic microbes carry any genes of a pathogenic nature?
- Has the strain been used for a number of years and entered on the European Qualified Presumption of Safety List (EQPS)?

Accuracy of microbe identification

If a probiotic product does not contain the species and strains that it claims, there may be a greater risk to the consumer due to uncertainty over the microbes' characteristics. Mis-labelling can be due to a number of reasons from reclassification of a microbe to inexperience of a lab technician and poor quality control.

Full identification of the strain should be included on the packaging of the product to include genus, species and strain code. This helps differentiate between species as not all species will have the same effect.

Pathogenic Genes

Each strain needs to be fully identified and tested to ensure that there are no pathogenic genes. Pathogenic genes can

cause a variety of conditions including food poisoning and toxin production. Having each strain lodged at a culture collection bank is vital to ensure that there is no genetic shift in the strain over time.

European Qualified Presumption of Safety List

A wide variety of microbial species are used in food and feed production. Some have a long history of apparent safe use, while others are less well understood and their use may represent a risk for consumers. A system was proposed for a pre-market safety assessment of selected groups of microorganisms leading to a "Qualified Presumption of Safety (QPS)". In essence this proposed that a safety assessment of a defined taxonomic group (e.g. genus or group of related species) could be made based on four pillars (establishing identity, body of knowledge, possible pathogenicity and end use)¹.

Research

How do you know that the strains you consume will have the effect you want them to? Even when research has shown a specific effect with a strain or product, it is difficult to know if it will definitely have that effect in all individuals. This is due to so much variation between conditions and individuals, however, research is certainly a very good indicator of the most likely effect, and is important. Research can take place in various forms including *in vitro*, gut models, animal models and full human clinical trials. It is not only efficacy research that is important; safety and toxicity work are also significant.

Multistrain and Multispecies

With over 500 different species of microflora in a healthy gut, it stands to reason that using a multistrain and multispecies product would be advantageous. Different species are found in various niches of the GI tract and exude various mechanism of action. This ensures multiple mechanisms of action and seeding of various niches within the GI tract. Timmermann and colleagues² found in 6 studies comparing single strain and multistrain probiotics that there is more evidence for multistrains being more effective than single strains.

Probiotics International Ltd

Here at Probiotics International we are dedicated to producing innovative research based products of the highest quality for humans and animals. Our unrivalled experience in manufacturing probiotic products for over 20 years, together with quality assurance and accreditation is second to none.



Probiotics should be tested by an independent, fully accredited laboratory to ensure the product meets its label claim.

Quality and Safety

Quality assurance is of utmost importance to us and we have strict quality control procedures in place. Our purpose built manufacturing site in the UK is certified to GMP standard and audited by British Standards to ISO 9001:2008. We have a fully documented quality management system in place which includes risk assessments, full HACCP analysis and quality control. We run a full traceability programme and all raw material and finished product batches are subject to quality control analysis to ensure the best possible quality throughout the production cycle and for the whole shelf life of the product. We operate a positive release system where raw materials are held in quarantine until testing is complete and finished products are ensured to have reached specification before being released from the warehouse.

All testing is carried out by independent, UKAS accredited labs.

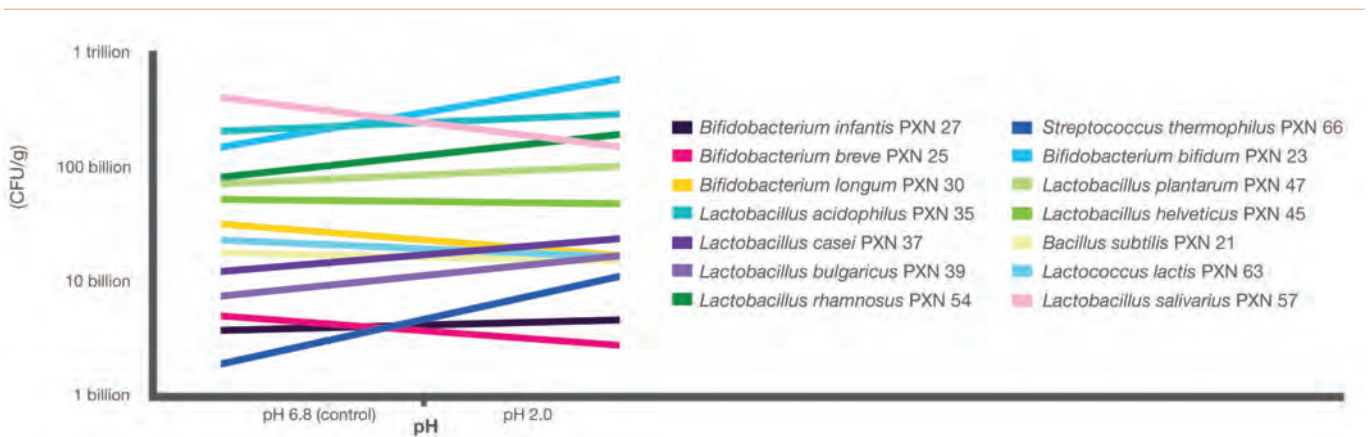
Our strains are all fermented individually on a batch by batch basis and carried out by high tech, fully validated machinery, operated by highly trained staff. Each strain is microencapsulated and freeze dried individually which affords their protection through the low acidity of the stomach (graph 1) and allows storage of the finished product under normal room temperature. All Protexin Health Care products are guaranteed at the end of the shelf life and

undergo full pharmaceutical stability testing in humidity and temperature controlled cabinets.

We operate an ongoing training programme with all of our production staff to ensure a highly skilled workforce. Our new purpose built, state of the art manufacturing site includes temperature and humidity controlled rooms with the latest machinery giving us the capability to produce a wide variety of finished products. All of our probiotic strains are fully identified and safe to use. The strains are all lodged at the National Collection for Industrial, Marine and Food Bacteria (culture collection bank) based in Aberdeen, UK, where we can ensure the safe reproducibility of the strain without genetic shift. The strains we use are also considered safe by the European Qualified Presumption of Safety Committee.

Research and Development

To ensure we remain at the forefront of the latest research we work with a number of leading research centres and universities in the UK and around the world. This research allows us to further understand how our products can help improve health and contribute towards new and innovative products in the future.



Graph 1: Acid stability of Protexin probiotic microorganisms *in vitro* unbuffered growth at pH 2.0 for 2 hours. There is no significant loss in the viability of the strains.



References

1. EFSA. 2007. Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. [online]. [Jan 2010]. Available from: http://www.efsa.europa.eu/en/scdocs/doc/sc_op_ej587_qps_en.pdf
2. Timmerman HM, Konig CJ, Mulder L, Rombouts FM, Beynen AC. 2004. Monostrain, multistrain and multispecies probiotics – A comparison of functionality and efficacy. *International Journal of Food Microbiology*. **96**: 219-233

About the author

Aileen Green BSc (Hons) MPhil

Aileen graduated with her degree in Animal Science from the University of Wales, Aberystwyth in 1996 and attained her masters, which focused on the benefits of probiotics in poultry, at the University of Liverpool whilst working in industry as a nutritionalist. Aileen joined Probiotics International Ltd in 2000 working initially as the Technical Manager before being promoted to Technical Director in 2003. She is currently the Research, Development and Quality Director.

Probiotics International Ltd is one of the largest manufacturers and suppliers of probiotic supplements for the healthcare, veterinary and animal health industry. Products are marketed under the brand name of Protexin.

As published in:

2010. *The Clinical Use of Probiotics*. Ed Barlow J. Probiotics International Ltd, United Kingdom.

©Probiotics International Ltd.

