PROBIOTIC SUPPLEMENT QUALITY: A MARKET SNAPSHOT

Viable count, strain identification and clinical evidence across 14 commercially available probiotic capsule supplements purchased in Ireland.

64% of probiotic supplements tested did not meet their stated CFU label claim.

Background and Study Objectives

Viable count, strain identification and supporting clinical evidence are distinct but complementary aspects of probiotic supplement quality. Published criteria for qualifying microorganisms as probiotics include, among other requirements, strain-level characterisation, supporting human clinical evidence, and viability at an efficacious dose throughout shelf life [1].

Key2Biotics conducted a pilot study of 14 commercially available probiotic capsule supplements, representing 14 different brands.

The study examined:

- how the measured viable microorganism count compared with the colony-forming units (CFU) quantity declared on the product label;
- whether the microorganisms were identified to strain level; and
- whether relevant published human clinical evidence could be identified for the declared strains and the health area for which the supplement was positioned.

One product and one batch were assessed from each brand. The findings therefore provide a point-in-time snapshot of the products tested and should not be interpreted as a comprehensive assessment of the wider probiotic supplement market.

Methods

Study design and product selection

Fourteen commercially available probiotic capsule supplements, representing 14 different brands, were included in this pilot study. One product was selected from each brand to maximise the breadth of the category represented.

Products were purchased from pharmacies and health stores in Ireland between 7 and 14 July 2026. All products were within their stated expiry date at the time of testing. The selected supplements included both domestic and international brands.

Immediately after purchase, the products were transported directly to the laboratory and stored at room temperature (approximately 20°C), consistent with the manufacturer's recommended storage conditions, until analysis. Laboratory testing was conducted between 14 July and 19 August 2026.

The study assessed one batch of one product from each brand. The results therefore relate only to the individual samples tested and should not be interpreted as an assessment of other batches, other products or the wider portfolio of any brand represented.

Viable microorganism enumeration

Viable microorganisms were quantified as CFU using modified ISO 15214:1998, modified ISO 7889:2026 and modified ISO 21527-2:2008, as appropriate to the microorganisms declared in each product.

Two independent sample preparations were analysed. Each was serially diluted and plated in technical duplicate. The reported CFU per dose was the mean of the 2 independent preparations.

Results were expressed as CFU per labelled daily dose and compared with the CFU quantity declared on the product label for the same dose.

Published literature reports an industry-accepted variability range of 20–30% or more for CFU enumeration methods [2]. To avoid treating differences within this reported range as failures, a 30% analytical allowance was applied in this pilot study. Products

with measured counts of at least 70% of the stated CFU quantity were considered to meet the label claim; products below 70% were considered not to meet the claim.

Strain identification

The probiotic microorganisms and strain designations declared for each product were recorded directly from the product label and accompanying packaging information.

A product was classified as providing strain-level identification when a specific strain designation was provided for the declared probiotic microorganism or microorganisms, rather than identification to genus and species level alone.

Clinical evidence assessment

For products providing strain-level identification, the published scientific literature was reviewed to identify human clinical studies involving the declared strain or strains.

Literature searches were conducted using a purpose-built internal evidence-review tool querying PubMed and Europe PMC. The studies identified by the tool were subsequently reviewed to assess their relevance to the declared strain, the dose investigated and the health area for which the supplement was positioned.

Product positioning was recorded from the product label and packaging and assigned to a standardised category for reporting. Clinical relevance was assessed against the original product positioning rather than the simplified reporting category.

A supplement was recorded as having relevant clinical evidence where published human clinical evidence relevant to the stated product positioning was identified for at least 1 declared strain. This did not indicate evidence for every declared strain or for the finished commercial product.

The purpose of this assessment was not to determine whether an individual commercial product was clinically effective. It was to establish whether the probiotic strain declared on the product label could be connected to published human clinical evidence relevant to the way in which the supplement was positioned.

Results

1. Does the supplement deliver its stated CFU count?

64% of probiotic supplements tested did not meet their stated CFU label claim.

Of the 14 supplements tested:

- 5 (36%) met their stated CFU label claim.
- 9 (64%) did not.

Measured viable counts varied substantially, ranging from less than 1% to 324% of the CFU quantity declared on the product label.

The shortfalls were not all marginal. Of the 9 supplements that did not meet their stated CFU label claim, 5 had measured viable counts of less than 2% of the declared quantity, including 3 with less than 1%. The overall finding was therefore not driven solely by marginal shortfalls.

At the other end of the range, 2 of the 5 supplements that met their stated CFU label claim showed substantial viable-count overage at the time of testing, with measured counts of 241% and 324% of the declared quantity. This may reflect the use of overage to help maintain the declared viable count over shelf life. However, because release-test counts and brand-held stability data were not available, it is not possible to determine whether the overage was intentional or whether these supplements will continue to meet their label claims through the end of shelf life.

Individual results are presented in Table 1.

Table 1. CFU label claim results for 14 probiotic supplements.

Brand	Expiry	Label claim (CFU/dose)	CFU measured (CFU/dose)	% of label claim	Meets label claim?
A	Jul 2028	1 billion	1.29 billion	129%	Yes
B	Jul 2027	1 billion	1.18 billion	118%	Yes
C	Jan 2027	4 billion	130,000	<1%	**No**
D	Mar 2027	20 billion	64.8 billion	324%	Yes
E	Oct 2027	8 billion	84 million	1%	**No**
F	Sep 2027	25 billion	19.9 billion	80%	Yes
G	Sep 2027	3 billion	180 million	6%	**No**
H	Jan 2028	25 billion	5.2 billion	21%	**No**
I	Jan 2027	50 billion	26.2 billion	52%	**No**
J	Oct 2027	5 billion	12.1 billion	241%	Yes
K	Nov 2027	20 billion	290 million	1%	**No**
L	Apr 2027	20 billion	100 million	<1%	**No**
M	Aug 2028	4 billion	1.4 million	<1%	**No**
N	Sep 2027	1 billion	580 million	58%	**No**

2. Are the probiotic strains identified?

79% of probiotic supplements provided strain-level identification.

Of the 14 probiotic supplements assessed, 11 (79%) identified the probiotic microorganisms to strain level, while 3 (21%) provided identification to species level only.

This distinction is important because probiotic effects are generally strain-specific. Evidence generated for 1 strain should not automatically be assumed to apply to another strain of the same species [1].

Strain-level identification enables the microorganisms declared in a supplement to be connected with published clinical evidence for those specific strains. For the 3 supplements that provided species-level identification only, it was not possible to determine whether evidence for a named strain applied to the microorganisms in the product.

Individual results are presented in Table 2.

Table 2. Strain identification results for 14 probiotic supplements.

Brand	No. of probiotics declared	Strain-level identification?
A	1	Yes
B	2	Yes
C	3	**No**
D	1	Yes
E	9	Yes
F	4	Yes
G	4	**No**
H	4	**No**
I	4	Yes
J	6	Yes
K	4	Yes
L	6	Yes
M	7	Yes
N	18	Yes

3. Does the clinical evidence match the health target on the label?

Relevant human clinical evidence was identified for at least 1 declared strain in 7 of the 14 supplements.

Clinical evidence could be assessed for the 11 supplements that provided strain-level identification. The remaining 3 supplements were not assessable because the declared microorganisms were identified to species level only.

Of the 11 supplements assessed, 7 had at least one strain with published clinical evidence relevant to the product's stated positioning. No relevant clinical evidence was identified for the remaining 4 supplements.

Identifying evidence for a declared strain is only the first step. The strain, dose, study population and health outcome must also be relevant to the way in which the supplement is positioned. Evidence involving the same strain in a different health area cannot automatically be considered relevant to the product.

This assessment establishes whether a connection can be made between the declared strains and relevant published human clinical evidence. It does not determine whether an individual commercial supplement is clinically effective.

Individual results are presented in Table 3.

Table 3. Clinical evidence results for 14 probiotic supplements.

Brand	Product positioning category	No. of probiotics	Clinical evidence relevant to stated product positioning?
A	Gut health	1	Yes
B	Urinary health	2	**No**
C	Gut health, Women's health, Support during and after antibiotic use	3	**Not assessable**
D	Support during antibiotic use	1	Yes
E	Gut health	9	**No**
F	Gut health	4	Yes
G	Gut health	4	**Not assessable**
H	Intimate health	4	**Not assessable**
I	Gut health	4	Yes
J	Gut health	6	Yes
K	Gut health, Immune health	4	**No**
L	Gut health, Support after antibiotic use	6	Yes
M	Gut health	7	**No**
N	Gut health	18	Yes

Note: “Yes” indicates that relevant human clinical evidence was identified for at least 1 declared strain. It does not indicate evidence for every declared strain or for the finished commercial product. “Not assessable” indicates that strain-level identification was not provided, meaning the declared microorganisms could not be reliably matched to published evidence for a specific strain.

Discussion

A quality probiotic supplement depends on several connected factors:

- the right strains for the intended application;
- clinical evidence relevant to those strains and the dose provided;
- an appropriate overage, supported by stability data, to account for expected losses over time; and
- formulation, packaging and storage conditions that maintain the declared viable count throughout shelf life.

The viable-count findings raise an important consumer transparency concern. Of the 14 supplements tested, 9 did not meet their stated CFU label claim and 5 contained less than 2% of the declared quantity. Where a supplement displays a CFU quantity on its label, consumers may reasonably understand that figure as describing the product they are purchasing within its stated shelf life. For many of the samples tested, the measured viable count was substantially lower.

Probiotic supplements can be expensive and are purchased with the expectation that they will provide live microorganisms for a particular purpose. This study did not assess clinical effectiveness and cannot determine whether an individual supplement will or will not produce a health benefit. However, where the viable dose is substantially below both the label claim and the dose supported by clinical evidence, there can be no assurance that the supplement will perform as expected.

Overage can be an important part of probiotic supplement development. It can help compensate for the loss of viable microorganisms during manufacture, distribution and storage. The substantial remaining overage observed in 2 supplements may reflect this approach, but release-test counts and internal stability data would be required to confirm it. Quality is not simply about providing the largest possible starting count; it is about using stability data to ensure that an appropriate viable count remains throughout shelf life.

Strain identification and clinical evidence are equally important. The finding that 11 of the 14 supplements provided strain-level identification is encouraging. For 7 of these 11 supplements, relevant published human clinical evidence was identified for at least 1 declared strain. This does not constitute clinical evidence for the finished commercial

product or indicate that every strain in a multi-strain supplement is clinically supported. The evidence must also be relevant to the strain, dose and intended application.

EU food-information legislation requires label information to be accurate, clear and not misleading [3]. The Food Safety Authority of Ireland also recommends that microorganism viability be determined throughout product shelf life to ensure that the information provided on the label remains accurate [4].

The expectation should therefore be straightforward: the strains are clearly identified, the evidence matches their intended use, and the viable count stated on the label is maintained throughout the product's shelf life.

References

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4. Food Safety Authority of Ireland (FSAI) (n.d.). Guidance on the assessment of the safety of microorganisms used in food supplements. https://www.fsai.ie/business-advice/food-supplements/guidance-on-assessment-of-safety-of-microorganisms

About this study

This pilot study was funded and conducted independently by Key2Biotics, a specialist probiotic and microbiome science company. Products were purchased commercially, and no represented brand funded, commissioned or had prior involvement in the study.

Brand identities have been anonymised because the purpose of the study is to provide a snapshot of the wider probiotic category rather than to evaluate or rank individual commercial brands.