Scientific Challenges in the Regulation of Probiotic Natural Health Products in Canada

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DISCLAIMER

I am not a lawyer.

Area of experience and expertise is pre-market assessment of Natural Health Products for safety, efficacy and quality.

Any opinions presented herein are my own and not necessarily shared by the Minister of Health or Health Canada.

Please ask about unfamiliar acronyms.
Stakeholder Feedback on the NHPD Probiotics Monograph

Why strain ABC and not XYZ?
Specifications not sufficiently detailed.
Why do cryoprotectants have to be declared as non-medicinal ingredients?
Why isn’t extrapolation to all strains supported?
Scientific Challenges with Probiotics

Lactic Acid Bacteria taxonomy.
Exclusion of transferrable antibiotic resistance.
Scientific basis for extrapolation from strain to species.
Validated biomarkers/surrogate endpoints for gut health/immunity.
Validated methods for quality assurance.
Short Term and Long Term Solutions

Despite significant scientific progress, data gaps remain. Interim solutions are required to allow market access for products with a recognized history of safe use. The NHPD Probiotics Monograph is being revised. An Abbreviated Labelling Standard for Live Microorganisms has also been published (revisions pending).

Provides a path to market while recognizing data gaps will require additional research and/or policy to resolve.
Lactic Acid Bacteria Taxonomy

Ongoing genomic research is changing the way some organisms are classified and named.
Older methodology will not always unambiguously distinguish probiotic strains from closely related species.
Health Canada’s interim solution:
  A recent identification report issued by an Internationally Recognized Culture Collection.
Research goal:
  A single, validated and cost-effective method for verification of species identity.
Transferrable Antibiotic Resistance

It is currently very difficult to estimate the actual risk posed by atypical antibiotic resistance.

Health Canada’s interim solution:

Recognition of EFSA’s QPS approach.
No strain may possess resistance known to be transferrable
Risk-based follow-up is possible post-market.

Research goals:
A single, validated and cost-effective method for exclusion of all genetic mechanism of resistance known to be transferrable.
A quantitative risk assessment regarding the contribution of probiotic products to community reservoirs of resistance.
Scientific Basis for Extrapolation from Strain to Species

There currently is no clear guidance regarding the scientific basis for extrapolating data from strains to an entire species.

Health Canada’s interim solution:
- A low-level claim defined by policy that can be supported by *in vitro* testing only.
- Full review option for innovative products with high-level claims.

Research goal:
- Identify the genetic determinants of probiotic efficacy.
Validated Biomarkers/Surrogate Endpoints for Gut Health

There are currently no rigorously validated biomarkers or surrogate endpoints for gut health in healthy individuals.

Health Canada’s interim solution:
- A low-level claim defined by policy that can be supported by *in vitro* testing only.
- Novel surrogate endpoints can be considered in full review for innovative products.

Research goal:
- Independent validation of surrogate endpoints for gut health in healthy individuals.
Validated Methods for Quality Assurance

There is currently very few internationally recognized methods for quality assurance of probiotic products.

Health Canada’s interim solution:
   Attestation to internally-verified methods, followed by a risk-based approach to site licensing.

Research goal:
   Independently validated and standardized methods for quality control.
Thank You!