

Taxonomic changes to *Lactobacillus* probiotics

Overview

A major international change in taxonomic naming protocol for *Lactobacillus spp.* is expected to occur in the near future^{1,2}. The first (genus) name of many probiotics currently called “Lactobacillus” will change, due to a long overdue correction required based on genomics and other considerations.

The new classification will be a more technologically precise vision of clusters of bacteria sharing common characteristics, resulting from a consensus between taxonomists. It will aim to ensure a shared and stable language of identifying many probiotics, and will be a historic event leading for the first time in the field of taxonomy to global effects on a pre-existing multi-billion dollar economy. The new classification, done correctly now, should prevent any further future changes.

Sponsors should be aware that this naming change is expected to affect *Lactobacillus* products internationally, including in Australia.

CMA have confirmed with the TGA that there will not be any changes in Australia until the taxonomic changes are officially published. The name changes will affect medicine sponsors, consumers and health professionals and as such it is expected that significant planning and consultation will be undertaken, with suitable transition periods.

What will be changing?

- **The *Lactobacillus* genus will be split up into 20 – 23 new genera.** To minimize confusion, these new genera will all start with the letter ‘L’. Each will be 4-7 letters longer than *Lactobacillus*.

Genus refers to the first name of the bacterium, i.e. *Lactobacillus*, and is a group of organisms based on similarity of qualities³. *Lactobacillus* are the largest lactic acid bacteria genus¹ and have previously been identified to share other qualities, such as being Gram-positive, mostly non-motile, catalase-negative, and non-spore-forming. However, the ~23 new genera will be based on genome-sequence-based taxonomy.

- **Species will not be changing¹**

Species refers to the second name of the bacterium (e.g., *acidophilus*) and is a more specific classification based on common qualities that differentiate them from other species with that genus³.

- **Strains will not be changing**

Strain refers to a more specific category of the bacterium, which separates members of the same species into subgroups based on one or more qualities that are distinct from other members of the species³.

The changes mean that only the first part of the name (genus) will appear differently for some probiotics that are currently given the name “Lactobacillus”; the remainder of the name will stay the same. It is currently expected that the following organisms will not be subjected to a change of name:

- *L. delbrueckii* (subspecies *lactis*, *bulgaricus* and *delbrueckii*), *L. amylovoris*, *L. helveticus*, *L. acidophilus* and *L. johnsonii*

When will it be changing?

As soon as the article announcing the name changes is published in the [*International Journal of Systematic and Evolutionary Microbiology*](#), the name changes will become valid, and can start to be examined by industry and regulators world-wide.

The TGA would conduct a public consultation and create educational materials and a transition period for products. Consultation is most likely to occur as part of the TGA's annual Low-Negligible risk consultation for Permissible Ingredients, which begins in the 3rd quarter of each year.

CMA has been in communication with the TGA and noted that, due to a large number of ingredients and products expected to be affected, a suitably lengthy transition period for labels is needed.

Why is the change required?

The *Lactobacillus* genus of probiotics includes over 230 widely heterogenous (different) species, with numbers growing rapidly. In June 2018, researchers published the result of a genome sequence analysis of 269 species², primarily belonging to the 25 families of the Lactobacillaceae and the Leuconostocaceae. The results showed a tree in which phylogeny and taxonomy were in serious disagreement and indicated that a renaming at genus level would be necessary.

The reclassification is anticipated to create new genera with a better homogeneity. Importantly it will create a stable number of genera that will accommodate future species without the need of a further reclassification. It will also allow for improved detection of distinct mechanisms of action of a specific genera⁴, thereby contributing to the identification of distinct health related benefits.

The International Committee on Systematics of Prokaryotes (ICSP) and the International Code of Nomenclature of Bacteria are responsible for the naming of bacteria. The subcommittee of the ICSP responsible for naming lactobacilli is the *Taxonomic Subcommittee for Lactobacilli, Bifidobacteria and Related Organisms*, and has been previously convened by the *Lactic Acid Bacteria Industrial Platform* (LABIP), the Industry Platform for EU sponsored research programs on Lactic Acid Bacteria.

Potential impacts

A collaborative strategy between the TGA and industry including educative programs in addition to a transition period, will be required to minimise confusion and successfully implement any changes.

Notable areas of potential impact may include:

- Changes to ARTG records – this may be able to be automated by the TGA or conducted manually by sponsors depending on preference;
- Changes to labelling requirements, consumer information – will be required internationally;
- Changes to technical, quality and marketing materials – will be required internationally;
- Changes to evidence – although there is expected to be a continuity of evidence based on species and strain, the name change would need to be noted in dossiers for review clarity;
- IP applications and patents – not expected to affect patents outright, however there may be some intellectual property issues during the transition period.
- submission of new applications for registration, listing and export of medicines, and notification of proprietary ingredients – amendments will need to be made where necessary.

Benefits

A classification system that better reflects genetic relatedness of the species is expected to reap longer term benefits. As evidence for clinical benefits accumulates, and investigations provide insight into probiotic mechanisms of action, a clearer image of functions associated with particular probiotics and probiotic groups should emerge.

The concept of core, shared benefits that were not strain-specific but in fact linked to higher taxonomic groupings is possible. More specificity will enable stronger and clearer evidence. Each new genus will be able to be better and more clearly understood, resulting in a vision of more targeted and functionally specific probiotics.

Another expected benefit is the use of more advanced and specific enumeration methods. The wide heterogeneity of the current *Lactobacillus* group causes issues with standardisation of enumeration techniques including through the use of plate cell count methods. The new taxonomy is expected to allow quicker and more discriminative and accurate results including using flow cytometry techniques.

Tools and Resources are upcoming

It is expected that organisations such as LAPIB, IPA, or the homepage of the Taxonomic Subcommittee for Lactobacilli, Bifidobacteria and Related Organisms will develop support tools and resources, including:

- Accessible documents outlining the taxonomic changes and why the changes were needed;
- Tools to help find the new taxonomy, including an app.

Resources:

- [The Lactobacillus Taxonomy change is coming: why, and how to make the most of it? \(microbiometimes\)](#)
- [International Journal of Systematic and Evolutionary Microbiology](#)
- [ICSP Subcommittee](#)
- [Lactic Acid Bacteria Industrial Platform \(LABIP\)](#)
- [Forthcoming changes in Lactobacillus taxonomy \(International Scientific Association of Probiotics and Prebiotics\)](#)
- TGA historical document: [Regulation impact statement: International harmonisation of ingredient names](#)

References

- ¹ Sanders 2018. Forthcoming changes in Lactobacillus taxonomy. ISAPP. <https://isappscience.org/forthcoming-changes-lactobacillus-taxonomy/>
- ² Salvetti et al., 2018. Comparative Genomics of the Genus Lactobacillus Reveals Robust Phylogroups That Provide the Basis for Reclassification. Appl. Environ. Microbiol. 2018 Aug 17;84(17). doi: 10.1128/AEM.00993-18.
- ³ Probiotic advisor (n.d.). Probiotic Nomenclature. <https://www.probioticadvisor.com/>
- ⁴ IPA (international probiotics association) 2019. Essentials to understanding taxonomy changes. <http://internationalprobiotics.org/>
- ⁵ Wittrock et al. 2019. A Genome-Based Species Taxonomy of the *Lactobacillus* Genus Complex
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