

To the attention of:

RE: Taxonomic Description of the genus Lactobacillus

The International Probiotics Association (IPA) and the supporting organizations (International Food additives Council, IFAC; European Food & Feed Cultures Association, EFFCA) are sharing this petition to inform the appropriate regulatory authorities of the recent taxonomic update to the genus *Lactobacillus*, to request regulatory discretion for labeling practices, to provide support needed for list updates including species formerly classified as *Lactobacillus* and to request feedback on estimated timelines to incorporate this change. It is crucial to note that this change is only a nomenclature change that has no impact on safety or efficacy of the microorganisms previously determined to be safe and suitable for use in foods and food supplements.

1) Lactobacillus Taxonomy update

As published by Zheng et al. (2020) ¹, the genus *Lactobacillus* had recently been comprised of 261 species, which were recognized as extremely diverse based on ecological, genomic and phenotypic analysis. The acknowledged diversity has led to the proposed reclassification of many species within *Lactobacillus* to group more appropriately, based on the above listed criteria, into 25 genera. This has resulted in a taxonomic update, published by the *International Journal of Systematic and Evolutionary Microbiology* in April of 2020.

The result of this update for a number of *Lactobacillus* spp. commonly used in foods and supplement as ingredients is already listed by EFSA in the table in Appendix 1, which identifies the former (classical) nomenclature and the updated genus and corresponding species (EFSA QPS-list²). As this list is not a comprehensive list of all taxonomy changes for *Lactobacillus*, we also offer the following resource for those additional species not housed within the EFSA QPS list. http://lactobacillus.uantwerpen.be/. It is imperative to recognize that taxonomic reclassification has resulted in *only* the genus names affected, and the species names remain constant and unchanged throughout this update. Furthermore, 38 species remain within the genus *Lactobacillus*, including e.g. *Lactobacillus acidophilus*, *Lactobacillus delbrueckii* subsp. *bulgaricus*, *Lactobacillus crispatus*, *Lactobacillus gasseri*, *Lactobacillus johnsonii*, *Lactobacillus helveticus*.

2) Regulatory Discretion Requested

In response to these taxonomic changes for *Lactobacillus*, the microbial ingredients, food cultures, direct fed microbials and probiotics* industries are faced with updating all bacterial nomenclature in all product literature, including labels and advertisements. At the same time, previously published scientific literature referenced in registration processes will use former nomenclature names. This presents the possibility of products containing microbial ingredients to be considered as misbranded or labeled improperly if regulatory agencies do not allow regulatory discretion in the immediate future. This request is extended to all import/export documents, regulatory dossiers, product labels, product informational materials and advertisements for these ingredients.



The microbial ingredients industries are working together to coordinate a global approach for updating all product documentation and literature, and to educate consumers on this nomenclature change. We request regulatory discretion for product labels that may contain updated taxonomic listings for the new genera, the existing taxonomic listing or at least, for the interim, those listing the genus name by the "L." abbreviation (e.g. *L. plantarum*). In a recently published scientific opinion, EFSA explicitly mentioned their intention to retain both names old and new of the microbial agent on the QPS list. Hence this serves as an interesting example to go forward with.

*It is recognized that the term probiotics is not globally accepted. It is IPA's intention to indicate that, while various terminology may be used around the globe, (live microorganisms, active cultures, etc.) those *Lactobacillus* spp. cultures added to foods, feed or dietary supplement type products with a technical or functional purpose, including *Lactobacillus*, are referred to probiotics as a category for the sake of this communication.

3) Microbial Ingredients List(s) Update(s) - Requested

To enable a smooth and harmonized global approach to updating *Lactobacillus* taxonomy, we are requesting that regulatory authorities update all lists that reference former *Lactobacillus* spp. with priority, in a clearly detailed and predetermined, timely manner. As the safety and characterisation of these live microorganisms has not changed, and only the taxonomy has been updated, it is anticipated that all previous approvals, or recognized ingredient lists can be updated to indicate also the new taxonomy without the need for further investigation. We are happy to help you update any relevant country-specific lists to reflect accurate taxonomic updates.

4) Estimated timelines - Feedback requested

We would very much appreciate receiving response to this petition with a concrete idea on the estimated timelines and actions for the discussed changes. We are happy to help connect different regulatory bodies together or with the scientific community to ensure greater harmonization, lessen disruptions on imports/exports and minimize consumer confusion with regards to same products being named differently from a country/jurisdiction to another.

We would like to thank you for the opportunity to enable global implementation of taxonomy changes for microbial ingredients. Our interest is to continue dialogue and encourage further participation and discussion to contribute to these important regulatory actions as they pertain to microbial ingredients.

We remain available to discuss any necessary clarifications of the contents within.

Sincerely yours,

George Paraskevakos, MBA

Executive Director

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<u>About IPA</u>: IPA is an international not-for-profit organization with members coming from all segments of the probiotic sector, including but not limited to industry, academia, researchers, scientists, health care professionals, and end users. Our membership includes the majority of the world's responsible manufacturers of live microorganisms and probiotics. IPA's goal is to provide a unique forum for the exchange of research, science and the latest breakthroughs in probiotic technology and new product development. IPA's mission is to promote the safe and efficacious use of probiotics worldwide. IPA also holds NGO status before Codex Alimentarius and is the "Global Voice of Probiotics".

Additionally, IPA works with government bodies and industry to assist in establishing scientific standards for probiotic supplements and functional foods. IPA also strives to educate consumers on the proven health benefits of probiotics, while ensuring they have access to safe, effective, and high-quality probiotics.

SUPPORTING ORGANIZATIONS OF THE TAXONOMY CHANGE PETITION FOR A HARMONIZED REVISION.



The International Food Additives Council (IFAC) is a global association representing manufacturers and users of food ingredients, including live microbial dietary ingredients (LMDI), starter cultures, and probiotics. IFAC strives to promote science-based regulations, standards, and specifications for food ingredients worldwide.

Contact: Robert Rankin, Executive Director



The European food & feed cultures association - EFFCA — is an European association representing manufacturers of microbials culture. EFFCA's aims to enhance public knowledge of the contribution the use of microbial cultures make within the food chain through accurate, fair and scientifically-based information; while discouraging any inappropriate promotion or misuse.

Contact: Loïc Gruson, General Secretary

¹ Zheng J., Wittouck S., Salvetti E. et al., (2020). A taxonomic note on the genus Lactobacillus: Description of 23 novel genera, emended description of the genus Lactobacillus Beijerink 1901, and union of Lactobacillaceae and Leuconostocaceae. https://doi.org/10.1099/ijsem.0.004107

² EFSA Journal 2020;18(7):6174; doi: 10.2903/j.efsa.2020.6174



APPENDIX 12

Taxonomic revision of the Lactobacillus genus for the QPS assessment and the QPS list

'Classical' denomination	'Updated' denomination
Lactobacillus acidophilus	Lactobacillus acidophilus
Lactobacillus alimentarius	Companilactobacillus alimentarius
Lactobacillus amylolyticus	Lactobacillus amylolyticus
Lactobacillus amylovorus	Lactobacillus amylovorous
Lactobacillus animalis	Ligilactobacillus animalis
Lactobacillus aviarius	Ligilactobacillus aviarius
Lactobacillus brevis	Levilactobacillus brevis
Lactobacillus buchneri	Lentilactobacillus buchneri
Lactobacillus casei	Lacticaseibacillus casei
Lactobacillus collinoides	Secundilactobacillus collinoides
Lactobacillus coryniformis	Loigolactobacillus coryniformis
Lactobacillus crispatus	Lactobacillus crispatus
Lactobacillus curvatus	Latilactobacillus curvatus
Lactobacillus delbrueckii	Lactobacillus delbrueckii
Lactobacillus dextrinicus	Lapidilactobacillus dextrinicus
Lactobacillus diolivorans	Lentilactobacillus dioliovorans
Lactobacillus farciminis	Companilactobacillus farciminis
Lactobacillus fermentum	Limosilactobacillus fermentum
Lactobacillus gallinarum	Lactobacillus gallinarum
Lactobacillus gasseri	Lactobacillus gasseri
Lactobacillus helveticus	Lactobacillus helveticus
Lactobacillus hilgardii	Lentilactobacillus hilgardii
Lactobacillus johnsonii	Lactobacillus johnsonii
Lactobacillus kefiranofaciens	Lactobacillus kefiranofaciens
Lactobacillus kefiri	Lentilactobacillus kefiri
Lactobacillus mucosae	Limosilactobacillus mucosae
Lactobacillus panis	Limosilactobacillus panis
Lactobacillus paracasei	Lacticaseibacillus paracasei
Lactobacillus paraplantarum	Lactiplantibacillus paraplantarum
Lactobacillus pentosus	Lactiplantibacillus pentosus
Lactobacillus plantarum	Lactiplantibacillus plantarum
Lactobacillus pontis	Limosilactobacillus pontis
Lactobacillus reuteri	Limosilactobacillus reuteri
Lactobacillus rhamnosus	Lacticaseibacillus rhamnosus
Lactobacillus sakei	Latilactobacillus sakei
Lactobacillus salivarius	Ligilactobacillus salivarius
Lactobacillus sanfranciscensis	Fructilactobacillus sanfranciscensis

The above table is not a comprehensive genera update, however, indicates majority of the most commonly used probiotics at the species level.