Brussels, 25 February 2021

TO THE ATTENTION OF: Food Control and Border Control Directorate Bulgarian Food Safety Agency 15 Pencho Slaveikov Blvd. BG-Sofia – 1606 National Centre of Public Health Protection 15 blvd. Ivan Ev. Geshov 1431 Sofia Public Health Directorate Ministry of Health 39 blvd. Alexander Stambolijsky 1000 Sofia

TO WHOM IT MAY CONCERN

SSOCIATION

RE: TAXONOMIC DESCRIPTION OF THE GENUS LACTOBACILLUS

The International Probiotics Association (IPA), comprised of global task forces from LATAM, APAC including China, Americas and Oceania, the International Probiotics Association Europe (IPA EU) and the supporting organizations (the International Food additives Council, IFAC, and the European Food & Feed Cultures Association, EFFCA) are sharing this letter to inform the regulatory authorities of the recent taxonomic update to the genus Lactobacillus, to request a smooth transition and advocate labeling practices, to provide the 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 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.

As these changes are science-based, the European Food Safety Authority qualified presumption of safety (QPS) list has already been updated on July 2nd 2020, and it includes the taxonomic revision of the Lactobacillus genus and EFSA states that "both the old and new names are retained" in the QPS list (<u>APPENDIX 1</u>)

It is important to notice that taxonomic reclassification has resulted in the genus names being changed, the species names remain unchanged. 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*. As this list is not a comprehensive list of all taxonomy changes for Lactobacillus, the following resources are provided for those additional species not housed within the EFSA QPS list.

<u>http://lactobacillus.ualberta.ca</u> <u>http://lactobacillus.uantwerpen.be/</u> <u>http://lactotax.embl.de/wuyts/lactotax/</u>



2) TRANSITION

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. During the transition, products containing microbial ingredients should not be considered as misbranded or labeled improperly. This applies also 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 with the exceptions as stated above regarding previously published scientific literature, and to educate consumers on this nomenclature change. During the transition, product labels 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). Moreover, recommending the use of the first letter of the genus for labelling purposes would allow consumers to make an informed choice when comparing different products using the same ingredient, avoiding confusion. 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 positive way to go forward with.

3) MICROBIAL INGREDIENTS LIST(S) UPDATE(S) - REQUESTED WHERE APPLICABLE

To enable a smooth and harmonized global approach to updating *Lactobacillus* taxonomy, other Authorities, where applicable, should communicate their position and update all lists that reference former *Lactobacillus* spp., in a clearly detailed manner, as done by EFSA. As the safety and characterization 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 also indicate the new taxonomy or the use of the first letter of the genus name without the need for further investigation. We are happy to help you update any relevant country-specific lists to reflect accurate taxonomic names.

4) CONCLUSIONS AND REQUEST OF FEEDBACK

We would like to thank you for the opportunity to enable global implementation of taxonomy changes for microbial ingredients. We remain at your disposal to facilitate connecting different authorities together and with the scientific community to ensure greater harmonization, both on import/export and for consumer information. 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.

Sincerely yours,

George Paraskevakos, MBA Executive Director

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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.





IPA Europe is a non-profit international association, based in Brussels, that represents the interests of the European Probiotic Industry in all discussions with the European Institutions, the European Food and Safety OCTATION Authority (EFSA), international institutions and national authorities, aiming to consolidate the probiotic category and boost EU competitiveness. Together, IPA & IPA Europe are engaged in establishing a clear framework for the use of the term probiotics, to better address the challenges the probiotic sector is facing and contribute actively to the international debate in the Codex Alimentarius.

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 makes 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.