Risk Assessment of Specific Strains of *Lactobacillus rhamnosus* Used as "Other Substances"

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Authors' contributions

This work was carried out in collaboration among all authors. The opinion has been assessed and approved by the panel on food additives, flavourings, processing aids, materials in contact with food and cosmetics of the norwegian scientific committee for food safety. All authors read and approved the final manuscript.

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ABSTRACT

The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) has, at the request of the Norwegian Food Safety Authority (Mattilsynet; NFSA), assessed the risk of "other substances" in food supplements sold in Norway. These risk assessments will provide NFSA with the scientific basis for regulation of the addition of "other substances" to food supplements and other foods.

"Other substances" are described in the food supplement directive 2002/46/EC as substances other than vitamins or minerals that have a nutritional and/or physiological effect. It is added mainly to food supplements, but also to other foods. VKM has not in this series of risk assessments of...
“other substances” evaluated any claimed beneficial effects from these substances, only possible adverse effects.

The present report is a risk assessment of Lactobacillus rhamnosus Rosell-11 ND, Lactobacillus rhamnosus W71, Lactobacillus rhamnosus GG and Lactobacillus rhamnosus Lr-329 based on previous risk assessments and also publications retrieved from literature search. The risk of the Lactobacillus strains listed above was assessed for the general population. However, in previous assessments of probiotics published by VKM, concerns have been identified for specific groups. Therefore, the risk was assessed for the age group with immature gastro-intestinal microbiota (age group 0-36 months), population with mature gastro-intestinal microbiota (>3 years) and vulnerable groups with mature gastro-intestinal tract. VKM has also assessed the risk of L. rhamnosus Rosell-11 ND, L. rhamnosus W71, L. rhamnosus GG and L. rhamnosus Lr-329 in food supplements and other foods independent of the dose and have assessed exposure in general terms.

VKM concludes that it is unlikely that L. rhamnosus Rosell-11 ND, L. rhamnosus W71, L. rhamnosus GG and L. rhamnosus Lr-329 would cause adverse health effects in the general healthy population with mature gastro-intestinal tract.

However, no data on long-term adverse effects on infants and young children were identified. As evidence is accruing that the early microbial composition of the neonatal gut is important for the development of the gut microbiota and the immune system of the growing child, it is not possible to exclude that a daily supply of a single particular bacterial strain over a prolonged period of time to an immature gastro-intestinal tract may have long-term, although still unknown, adverse effects on that development.

Keywords: Adverse health effect; negative health effect; Norwegian food safety authority; Norwegian scientific committee for food safety; other substances; risk assessment; VKM; L. rhamnosus Rosell-11 ND; L. rhamnosus W71; L. rhamnosus GG; L. rhamnosus Lr-329; food supplement.

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NOTE: This work was carried out in collaboration between all authors. The opinion has been assessed and approved by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of VKM. All authors read and approved the final manuscript.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.