



Assessment of Benefits and Risks of Probiotics in Processed Cereal-based Baby Foods *Lactobacillus Paracasei* ssp. *Paracasei* F19

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Authors' contributions

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Grey Literature

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ABSTRACT

The Norwegian Scientific Committee for Food Safety (VKM) has appointed an ad hoc-group of experts to answer a request from the Norwegian Food Safety Authority regarding benefit and risk assessment of *Lactobacillus paracasei* ssp. *paracasei* F19 (F19) in processed cerealbased baby foods intended for small children 1-3 years. This assessment is based on the literature provided by the notifier as well as that found by a MEDLINE search.

A notification regarding two products of processed cereal-based baby foods (hereafter called cereals), intended for small children and supplemented with the bacterium F19 initiated this work.

A daily supply of a monoculture of a particular bacterial strain in large quantities to an age group without a fully established intestinal flora, may have unknown adverse effects. There are however, to our knowledge, no studies investigating possible short or long term adverse health effects of F19 in processed cereal-based baby food given to children 13 months onwards.

The documentation and information provided by the notifier regarding the genetic stability of F19 in the two products during processing and storage, is considered insufficient and does not allow any conclusions to be drawn.

Moreover, the documentation obtained is not conclusive regarding the antibiotic resistance pattern of the bacterial strain used in the products in question, as the information on different antibiotics is partly inconsistent. The information about specific localization (chromosomal, plasmid) of the resistance genes is not sufficient.

Studies demonstrate that F19, as well as other bacterial strains considered probiotic, is able to “crosstalk” with enterocytes in mice and that the result of the “crosstalk” depends upon the microbiota present. Whether F19 has a similar “crosstalk-profile” in humans is unknown. However, as the strain is originally of human origin, it seems reasonable to assume that such “crosstalk” may occur. Thus, before giving F19 daily for months and years, it seems reasonable to ask for additional molecular and physiological studies to unravel the functional impact of possible changes in genetic expression in children.

Lactobacillus infections do occasionally occur, mainly as bacteremia, endocarditis and localized infections (e.g. abscesses, peritonitis, and meningitis) in patients with severe underlying diseases. Most of them are elderly, but children are not excluded. The species most often isolated are *L. casei* and *L. rhamnosus*, followed by *L. paracasei*.

The increasing use of immunosuppressive therapy and broad spectrum antibiotics which are ineffective against *Lactobacillus*, might increase the importance of these bacteria as possible pathogens. In order to be able to draw any conclusions regarding beneficial effects of F19, there is a need for randomized placebo-controlled studies in larger populations and in the relevant age group.

According to EFSA, *Lactobacillus paracasei* ssp. *paracasei* F19 is sufficiently characterized. The documentation provided is, however, not sufficient to claim positive health effects and thus F19 is not proven to be probiotic.

There are no published dose-response studies of F19 in children, neither regarding survival of F19 in the gastrointestinal tract, nor possible negative health effects. Thus the potential for negative health effects as e.g. spreading of antimicrobial resistance or unfavourable impact on the genetic expression in children related to the frequency and/or dose of a monoculture of F19 cannot be assessed.

Keywords: VKM; assessment; Norwegian Scientific Committee for Food Safety; baby foods.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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