



Assessment of Benefits and Risks of Probiotics in Processed Cerealbased Baby Foods Bifidobacterium Lactis Bb12

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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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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 *B. lactis* Bb12 in baby foods focusing on the age groups 4-6 months, 6-12 months and 1-3 years. This assessment is based on the literature provided by the notifier as well as that found by a MEDLINE search.

An notification for use of processed cereal-based baby foods (from now on called cereals) intended for infants and small children supplemented with the microorganism *Bifidobacterium lactis* (*B. lactis*) Bb12 in Norway initiated this work.

Studies of potential hazards and positive health effects from cereals containing *B. lactis* Bb12 intended for infants and young children have not been reported in the available literature. However, reports on safety of and positive health effects from infant and follow on formula supplemented with *B. lactis* Bb12 are available and have been assessed by VKM. In most of these clinical studies *B. lactis* Bb12 was administered in combination with other probiotic strains.

Clinical studies report no serious adverse events of infant formula supplemented with *B. lactis* Bb12. The effect of long term daily consumption of such supplemented formula by the actual age groups is not known.

A few studies have demonstrated some effect of supplementing baby food with probiotics, including *B. lactis* Bb12, on diarrhoea and atopic eczema while other studies do not show such effects. Thus, the scientific evidence for a favourable effect of supplementing formula or solid food with *B. lactis* Bb12, is weak and in some cases lacking.

There are no studies demonstrating a positive effect of cereals supplemented with *B. lactis* Bb12 intended for infants and small children.

Several health claims related to probiotics have been assessed by EFSA, including claims on reduction of gastro-intestinal discomfort, normal functioning of the alimentary tract, building of the natural intestinal barrier, improvement of the general immunity, mental and cognitive developments of children and immune system of children during growth. In the opinions so far, EFSA has concluded that a cause and effect relationship has not been established between the consumption of the probiotic containing products and the claimed effect. None of the products assessed so far contained *B. lactis* Bb12 (1 November 2009).

Commercially produced cereals are frequent given to infants and small children in Norway from an early age and this is particularly important for the establishment of the intestinal bacterial flora and the development of the intestinal mucosal immune system. According to the notifier, one portion (25gram) of the cereal powder contains 1×10^9 *B. lactis* Bb12 in monoculture. Taking into consideration that the daily intake is often greater than one portion of cereals, even in infants below 6 months of age, this would represent a daily intake of $1-2 \times 10^9$ cfu *B. lactis* Bb12 for an infant 4-6 months and even more in infants above 6 months. If a considerable amount of the *B. lactis* Bb12 survives the transport to the small intestine, it would represent a dominating and monocultural supply, often several times a day, to the small intestine. The immaturity and vulnerability of the intestinal microbiota and the immune system makes the two lowest age groups, 4 – 6 and 6 – 12 months, at the highest risk of unwanted health effects due to the daily intake of probiotics.

Keywords: VKM; assessment; Norwegian Scientific Committee for Food Safety; *Bifidobacterium lactis* Bb12; baby food.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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