Health Risk Assessment of a Food Supplement Containing *Lactobacillus reuteri* Protectis®

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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 Biological Hazards of VKM. All authors read and approved the final manuscript.

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ABSTRACT

The Norwegian Scientific Committee for Food Safety (VKM) appointed a working group of experts to answer a request from the Norwegian Food Safety Authority regarding health risk assessment of *Lactobacillus reuteri* Protectis® in a food supplement intended for use by infants and young children. The mandate of this health risk assessment was not to evaluate the health claims related to the products as such health claims are assessed by EFSA.

The specific strain DSM 17938 is a “daughter strain” of the strain ATCC 55730 which was originally isolated from normal human milk. ATCC 55730 harbours two plasmids carrying transferable resistance genes against tetracycline and lincosamides respectively. The “daughter strain” DSM 17938 was established in 2008 by curing the ATCC 55730 for these plasmids, but is in all other respects claimed to be identical to ATCC 55730 and bioequivalence of the two strains has been suggested. The strain DSM 17938 was still resistant to tetracycline (although at a considerably lower level than ATCC 55730) and a number of other antibiotics, but these resistances were all

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considered being intrinsic by FBO. The absence of possible transferable/mobile genes has, to our knowledge, not been confirmed in later studies.

We are not aware of any data indicating that L. reuteri has been the cause of serious human diseases – and none of the studies examined has reported any adverse or undesirable short time effects. It has also been used in preterm infants with dosage corresponding to the actual recommended doses - without reporting any adverse, short term reaction. There is therefore no evidence leading to consider the strain DSM 17938 at the dosage recommended as unsafe.

However, more long-term data are still lacking and the long-term safety for the age groups considered in this assessment cannot be established. As evidence is accruing that the early microbial composition of the infant gut is important for the development of the gut flora and the immune system of the growing child, it is not possible to exclude that a daily supply of a particular bacterial strain over a prolonged period of time to an immature gastro-intestinal tract may have long-term, albeit still unknown, adverse effects on its development.

As the long-term data are lacking it is not possible to answer whether the amount of the food supplement or the age of the infant or young child is of importance.

However, if later long-term data should reveal any adverse reaction, it is reasonable to assume that the actual age group will be the most vulnerable.

As the safety was not entirely established, the question of whether there are any vulnerable groups (i.e. premature, infants or children with diseases) where there are health risks associated with the intake of Lactobacillus reuteri Protectis®, as a food supplement was not considered.

Keywords: VKM; risk assessment; Norwegian scientific committee for food safety; Norwegian environment agency; lactobacillus reuteri DSM 17938; probiotic; food supplement; infant; neonate; young children; microbiome.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.