Norwegian Scientific Committee for Food Safety

Background

Probiotics are defined as living microorganisms with positive effects on human and animal health.

The beneficial effects of probiotics are claimed to be:
• Antimicrobial effects that can result in reduced capacity and reduced growth of pathogenic bacteria,
• detoxifying effect that may include inactivation or neutralizing substances that may be harmful to the host,
• Immunological effect regarding positive stimulation of the immune system.

VKM has conducted a number of risk assessments of probiotics on behalf of the Norwegian Food Safety Authority (NFSA). This has resulted in 5 risk assessments and two scientific papers published in international journals. With the exception of one report, which was of general nature, reports were assessing benefits / risks of specific commercial products. NFSA's requests were partly due to applications from the manufacturers of these products. Panel for biological hazards and Panel for food additives have been involved in all these cases and have learned through these assessments which elements should be included in the evaluation of a probiotic product and how they should be judged.

Given that probiotics are increasingly used and advertised, it is reasonable to assume there will be more applications for introduction of new probiotic products. We expect therefore more requests from Norwegian Food Safety Authority. In order to standardize and simplify this type of assessments as much as possible, we suggested outlining a general guideline that can be used for the evaluation of probiotic products.

Such a guideline may be useful for:
• Norwegian Food Safety Authority, which receive the required documentation. It is possible that guidelines will be sufficient for the Authority, in certain cases, to immediately determine the outcome of the application.
• VKM, which could rationalize this type of risk assessment and thus shorten the processing time.
• Producers who thus know the requirements for approval,

Such a general guideline could possibly, with the necessary modifications, also be used by Panel for animal feed and Panel for animal health and welfare.

We expect the guidelines to be updated regularly as new data become presented and relevant version is going to be available at www.vkm.no.

Terms of reference

The Panel has decided on the following terms of reference:

To develop a guidance document on the scientific requirements and clarifications of the mandatory requests and other information that can be forwarded by the producer of the probiotic product. Health claims related to gut and immune function are not a part of mandate.