Proposal Number: P1028 – Infant Formula
Organisation Name: [redacted]

[redacted]

Dear Sir/Madam,

RE: Submission of comments to P1028 – Infant formula in context of the use of Probiotics in infant formula products.

We, Chr. Hansen, would formally like to submit comment to Proposal P1028 – Infant Formula with specific focus on section 5 Safety and Food Technology (SD1); sub-section 5.4 L (+) lactic acid producing microorganisms (page 41).

The current FSANZ proposal requires a Novel food pre-market assessment on microorganism used as probiotics prior to its addition into infant formula products. We seek further elaboration and clarification regarding this new approach especially given the circumstance that probiotics, or beneficial L(+) lactic acid bacteria are present in breast milk and have been part of an infants' nutrition worldwide including Australia and New Zealand.

We would also like to bring to attention that probiotics, or beneficial L(+) lactic acid bacteria, commonly used in infant formula, are with long history of use in human population including infants, scientifically researched, and are produced under Good Manufacturing Practice and relevant Quality standards to the local requirements. Additionally, many of these strains and species have received Generally Recognized as Safe (GRAS) status by the US Food and Drug Administration (FDA) as well as Qualified Presumption of Safety (QPS) status since 2007 by the European Food Safety Authority (EFSA) in Europe.

We therefore put forth our comments below in support of the above:

1. **<u>Exemption for current use probiotic strains in existing infant formula products</u>**
   There are infant formula containing probiotic on the shelves across Australia and New Zealand today. These products are accessible to the consumers and families will continue to require these products. We kindly request FSANZ to consider these products as an exception to the rule by allowing the "grandfathering-in" of the probiotic strains used in existing infant formula products. This will enable a continuous supply of product to market and avoid any potential consumer confusion over these changes.

2. Clarification on the approach of requiring novel food pre-market assessment

We request more clarity on the whole requirement, process, time, outcomes to be expected and the readiness of the current systems so we/Industry can understand better on this would impact the us as an international probiotic ingredient manufacturer.

- In the current published record of views from the ACNF, some lactic acid bacteria/probiotics have been evaluated in dairy applications. Would a new submission be then expected on genus/ species/ strain level for probiotic strains added to infant formula products?
- Who should be the applicant for the novel food pre-market assessment?

3. Worldwide use of Probiotics in infant formula products

We urge FSANZ to consider that there many infant formula products containing probiotics around the world and these products have been consumed by Infants for a long period of time. Many probiotics of L(+)lactic acid bacteria are used in Infant formula as the basis per Codex Alimentarius, which also means that there is a long history of consumption of probiotics in the form of infant nutritional formulae. We urge FSANZ to consider the current use of probiotics on an international basis, and the fact that it is a substance ordinarily found in human milk.

The need for pre-market novel food assessment for as novel food will have a large effect on the industry and will result in a large influx of applications. We respectfully request FSANZ to consider an exemption on the Novel assessment for current probiotics already used in infant formula. For new probiotics or Novel probiotics, we request for a Transitional period of five (5) years for cases where a novel food pre-market assessment be required. This will help facilitate continuous supply of products in the marketplace while industry gears up to meet the requirements for future products.

We appreciate your consideration and time.

Thank you.