CONTENTS

Executive Summary

Health claim petition/applied health claim

Details of the petitioner/submitter

1-scientific data

- 1-1 introduction
- 1-2 current stage of knowledge
- 1-3 presentation of the product/ details of the product
- 1-3-1 definition/descritption of the product
- 1-3-2 source/raw material and production
- 1-3-3 regulatory context/situation
- 1-3-4 composition of the product/ list of ingredients and nutrient values
- 1-3-5 anticipated consumption and suggested vector foods
- 1-3-5 target population
- 1-3-6 suggested claims
- 1-3-7 ingenuity/novelty of the product in comparison with the similar products in the market
- 1-3-8 I information on the anticipated consumption of the product and actual consumption of the similar products already on the market
- 1-4 nutritional assessment/evaluation
- 1-4-1 nutritional benefits

- 1-4-2 rational/justification of the recommended dose of intake
- 1-4-3 studies done with the product (in vivo, in vitro
- 1-4-4 scientific substantiation of the health claims
- 1-4-5 legality of the health claims
- 1-5 toxicological and microbiological assessment/evaluation
- 1-5-1 safety of the use (no adverse or harmful effects, upper safty limits, risk assessment
- 1-4-2 toxicological studies performed with the product (mutagenicity, teratogenicity, pathogenicity of the strains, potential allergens)
- 1-4-3 contaminant analyses/analyses of undesirable substances (antinutrients, heavy metals, pesticides and micro-organisms)

2-: technological data

- 2-1 chemical formula
- 2-2 raw material (list, source and traceability)
- 2-3 production process
- 2-4 physico-chemical characteristics
- 2-5 quality control of the product(composition, stability, defining the shelf ife)
- 2-6 packaging and storage
- 2-7 labeling details (health claim, composition, best before date, recommended dose,
- 2-8 technical data

3- potential follow-up of the consumption (market and consumer analysis)

4.in-depth literature search

- 4.1 Generic data
- 4.2 Product Specific data

Conclusions