

## SUBMISSION to Food Standards Australia New Zealand (FSANZ)

### Consultation Paper – Proposal P1028

#### Regulation of Infant formula – Infant formula products for special dietary use

Submission from paediatric dietitians with a special interest in food allergy and intolerance, at Starship Child Health, Auckland, Nelson Hospital and Whangarei Hospital, New Zealand

Jennifer Heyward  
Paediatric Dietitian  
Starship Child Health  
Address: Paediatric Dietitians  
Level 8, Building 1  
Auckland City Hospital  
Private Bag 92 024  
Auckland 1142

Telephone:  
Mobile:  
Fax:  
Email:

Helen Norrish  
Paediatric Dietitian  
Nelson Hospital  
Address: Nutrition & Dietetic Services  
Nelson Hospital  
115 Kawai Street  
Nelson

Telephone:  
Mobile:  
Fax:  
Email:

Rhonda Akroyd  
Paediatric Dietitian  
Starship Child Health  
Address: Paediatric Dietitians  
Level 8, Building 1  
Auckland City Hospital  
Private Bag 92 024  
Auckland 1142

Telephone:  
Mobile:  
Fax:  
Email:

Mary McNab  
Paediatric Dietitian  
Whangarei Hospital  
Address: Child Health Centre  
Whangarei Hospital  
Maunu Road  
Private Bag 9742  
Whangarei 0148

Telephone:  
Mobile:  
Fax:  
Email:

**Q5 Are there any issues with the current definition for protein substitutes?**

Yes.

- The term hydrolyzed protein fulfils the definition of protein substitute. In food allergy and malabsorptive conditions the type of protein substitute and degree of hydrolysis are very important. These are the major factors which determine which product is suitable for the clinical condition.
- Hence the type of protein substitute and extent of protein hydrolysis needs to be clearly stated on product labelling.

**Q6 Is there a benefit to defining one or more of the following in the Code:**

- Hypo-allergenic formula
- Partially hydrolysed formula
- Extensively hydrolysed formula
- Amino acid-based infant formula?

Yes

**If yes, what are the benefits of including these definitions? And what should be the key elements of each definition?**

- Definitions should be given for the different types of protein substitutes as their composition is different and degree of hydrolysis can be different. This affects their suitability for use in different medical conditions.
- Clinicians need specific details on labels and product information regarding the composition of the protein substitute in order to prescribe the appropriate formula for the infant or child's clinical condition.
- In New Zealand and internationally there are defined criteria which specify the type of modified protein formula appropriate as the first line treatment in cow's milk allergy and for other allergic or malabsorptive conditions.<sup>1,5,6,7</sup>
- In some conditions an amino acid formula should be used e.g. for eosinophilic oesophagitis, for anaphylactic reactions to cow's milk, whereas an extensively hydrolysed formula should be given for an infant under 6 months of age with a non-anaphylactic reaction to cow's milk.
- Hypoallergenic labelling of partially hydrolysed formulas is permitted in some countries. This can create confusion among health professionals and parents, and carries a potential risk of a life threatening reaction if a cow's milk allergic child is given a partially hydrolyzed formula when it is labelled as hypoallergenic/ HA.
- Partially hydrolyzed formulas are not suitable for infants and children with cow's milk protein allergy
- Van den Plaas *et al* state "because the wording of hypoallergenicity abbreviated as HA, has different meaning in different parts of the world, we should no longer use the wording hypoallergenic in scientific papers to avoid confusion, and instead use "partial" or "extensive" hydrolysates".<sup>3</sup>

#### **Q6 Benefit to defining Hypo-allergenic formula:**

- It will explain the different types of protein and extent of hydrolysis.
- To assist in interpretation of use of the product in food allergy management.

#### **Key elements of definition of hypoallergenic formula**

- Hypoallergenic formulas are processed by enzymatic hydrolysis of different protein sources such as bovine casein/whey and soy followed by further processing such as heat treatment and/or ultrafiltration, or they are based on amino acid mixtures.<sup>4</sup>
- The products have been classified according to the degree of protein hydrolysis as extensively or partially hydrolysed protein.<sup>4</sup>
- It is recommended that dietary products for treatment of cow's milk protein allergy in infants should be tolerated by at least 90% (with 95% confidence) of infants with documented cow's milk protein allergy. Some extensively hydrolysed products and amino-acid based products have met these criteria.<sup>1, 4, 5.</sup>

#### **Q6 Benefit to defining Extensively hydrolysed formula**

- A definition of an extensively hydrolysed formula (eHF) will enable the products with the appropriate protein structure to be easily identified as eHF.
- This means the eHF can be identified as an appropriate formula for infants and children with cow's milk allergy, other allergic or malabsorptive conditions.
- It will enable identification of products which contain some proteins in the higher molecular weight range that may be inappropriate for use in cow's milk protein allergy or other medical conditions.

#### **Key elements of definition of Extensively hydrolysed formula (eHF)**

- Specify the source and type of protein used e.g. cow's milk whey, casein.
- A description of the components and hydrolysis of the protein.  
This includes the molecular weight, peptide size, and allergenicity of the proteins.
- Define the molecular weight of the proteins which are considered to be in the eHF range.  
i.e. Dalton particle size Da or kD.  
e.g. peptides in eHF have, in >90%, a molecular weight of <3 kD. <sup>2, 3</sup>
- For treatment of proven cow's milk protein allergy the eHF should be tolerated by 90% of infants with cow's milk protein allergy (CMPA) with a 95% confidence interval.<sup>1</sup>
- Amino acid (AA) and extensively hydrolysed formulas(eHF) are suitable to treat CMPA.<sup>1, 2, 5</sup>

#### **Q6 Benefit to defining Amino acid based formula**

- A definition of an amino acid is important to ensure the formula will only contain pure amino acids as the protein source.
- This is important to ensure safety of use in infants and children who have anaphylactic and severe reactions to cow's milk protein and those who may also react to eHF.

#### **Key elements of definition of amino acid formula**

- Pure amino acids

#### **Benefit to defining Partially hydrolysed formula (pHF)**

- To identify the different types of protein sources and the extent of hydrolysis
- To specify the peptide size of all the proteins.
- To enable identification of products with proteins in the partially hydrolyzed range that will not be appropriate for treatment of cow's milk protein allergy and other medical conditions where this type of formula is contra-indicated

#### **Key elements of definition of partially hydrolysed formula**

- Specify the source and type of protein used e.g. cow's milk whey, casein.
- State the range of molecular weight of all the proteins  
e.g. pHFs contain peptides that have a molecular weight of generally <5kD  
(ranges between 3 and 10 kD).<sup>3</sup>
- For treatment of cow's milk allergy state that partially hydrolyzed formulas are not suitable for infants and children with proven cow's milk allergy

It should be noted that there is no consistent convincing evidence to support a protective role for partially hydrolysed formulas (usually labelled 'HA' or Hypoallergenic) or extensively hydrolysed formulas for the prevention of eczema, food allergy, asthma or allergic rhinitis in infants or children.<sup>8</sup>

Jennifer Heyward  
Paediatric Dietitian  
Starship Child Health  
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