

Nutrition Services Practice Change Notice

Hydrolyzed Formulas and Allergy Prevention

Hydrolyzed infant formulas are no longer recommended for allergy prevention

Nutrition Services

June 2022

This statement is intended for health professionals that provide guidance around infant formula use.

Practice Change Summary

Nutrition Services, Alberta Health Services, no longer recommends feeding a hydrolyzed infant formula (i.e., partially hydrolyzed 100% whey or extensively hydrolyzed casein) versus a standard cow's milk infant formula for allergy prevention in infants at high risk of allergy.

This change is based on conclusions from systematic reviews,¹⁻³ and a meta-analysis.¹ Recent statements from the Canadian Paediatric Society,⁴ the American Academy of Pediatrics,⁵ the European Academy of Allergy and Clinical Immunology (EAACI),⁶ and the Australasian Society of Clinical Immunology and Allergy (ASCIA)⁷ also reflect these conclusions.

Background

Research and recommendations around the use of hydrolyzed formulas for allergy prevention has evolved over the years.

Previous Guidance

Prior to this practice change, Nutrition Services' guidance (e.g., Infant Formulas for Healthy Term Infants Compendium and Summary Sheet [2018/2019]) supported feeding a partially hydrolyzed 100% whey or extensively hydrolyzed casein infant formula to reduce the risk of developing allergies in non-exclusively breastfed infants at high risk of allergy, and included statements such as:

- There is some evidence that for infants at high risk of allergy, who are not exclusively breastfed, using a partially hydrolyzed 100% whey infant formula instead of a standard cow's milk infant formula in the first 6 months of life may reduce the risk of developing an allergy.⁸⁻¹¹
- For infants who are not breastfed or are partially breastfed and are at high risk of allergy, some research shows an extensively hydrolyzed casein infant formula may reduce the risk of developing an allergy (compared to a standard cow's milk formula).^{8,10,12,13}
- For infants who are not breastfed or are partially breastfed and are at high risk of allergy, there is limited evidence that feeding with a hydrolyzed formula (i.e. extensively hydrolyzed casein infant formula or a partially hydrolyzed 100% whey infant formula) as compared to a standard cow's milk formula, can help reduce the risk of allergic disease, particularly eczema^{8,9,14-17} if used for the first 6 months of life.^{12,13,18,19}

Current Evidence

More recent analyses of the research on hydrolyzed formulas have weakened the previous conclusions⁵ and determined there is insufficient evidence to support feeding either a partially hydrolyzed whey or extensively hydrolyzed casein formula to prevent allergic disease.⁴

- One meta-analysis found no consistent evidence that partially or extensively hydrolyzed formulas reduce the risk of allergic disease (eczema, wheeze, allergic rhinitis, food allergy) compared with standard cow's milk formula in infants at high risk of allergy.¹ It also reported conflict of interest, high statistical heterogeneity and high or unclear risk of bias in most included studies.¹
- The most recent Cochrane review on this topic determined that irrespective of the risk of allergic disease, there is no evidence to support feeding a hydrolyzed formula compared with a standard cow's milk formula or with exclusive breastfeeding for the prevention of infant or childhood allergic disease, asthma, eczema, rhinitis, or infant food allergy. In addition, the quality of evidence included was assessed to be very low.³
- A recent systematic review reported a high risk of bias, high loss to follow-up, potential confounding, and lack of robust diagnostic criteria, and concluded there is little to no effect of hydrolyzed formulas compared with standard cow's milk formula on the risk of food allergy in infants at high risk of allergy.²

Based on these conclusions, pediatric and allergy organizations have amended their guidelines.

- In the UK, the Committee on Toxicity concluded that available evidence does not support the use of either partially hydrolyzed or extensively hydrolyzed formula to influence the risk of developing allergic disease²⁰ and the British Society for Allergy and Clinical Immunology recommends using a standard cow's milk formula rather than a hypoallergenic formula when breastmilk is not available.²¹
- The American Academy of Pediatrics changed its conclusion from "there was modest evidence" to "there is a lack of evidence" that the use of either partially or extensively hydrolyzed formula prevents atopic dermatitis in formula-fed or initially breastfed high-risk infants.⁵
- The Australasian Society of Clinical Immunology and Allergy^{7,22} and the Canadian Paediatric Society⁴ state that the use of hydrolyzed formulas for the prevention of allergic disease is not recommended.
- A consensus statement from the American Academy of Allergy, Asthma, and Immunology, the American College of Allergy, Asthma, and Immunology, and the Canadian Society for Allergy and Clinical Immunology advises against recommending the use of any hydrolyzed formula for the prevention of food allergy.²³

Current Recommendations

Breastmilk

- Promote and support breastfeeding for up to 2 years and beyond, regardless of issues pertaining to food allergy prevention.⁴ Breastfeeding is recognized as the unequalled way to provide optimal nutritional, immunological and emotional nurturing of infants.²⁴

Infant formulas

- Intact standard cow's milk-based infant formula: recommended for both low and high-risk infants⁴ until 9–12 months when parents/caregivers are unable to or have decided not to exclusively or partially feed breastmilk.²⁵
- Partially hydrolyzed 100% whey infant formula: not intended to be used for the treatment of any allergic condition or disease.²⁶ Although there is little evidence for any benefit of protein hydrolysates to the digestive system of infants compared to standard cow's milk-based formula,²⁷ parents may choose an infant formula with partially hydrolyzed 100% whey protein according to their preference.
- Extensively hydrolyzed casein infant formula: appropriate for formula-fed infants with diagnosed allergy to cow's milk^{27–30} or soy protein,²⁷ or malabsorption syndromes.²⁷

Impacted Documents

- Infant Formulas for Healthy Term Infants - Summary Sheet: in revision; estimated completion July 2022.
- Infant Formulas for Healthy Term Infants—Compendium: to be retired July 2022.
- Other professional education materials (e.g., Public Health Nutrition Modules): in revision; estimated completion Fall 2022.
- Zone documents: zone health professionals to update as appropriate.

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