Nutrition Services
Public Health Nutrition

Infant Formulas

Ingredients and Indications

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Contact and Acknowledgements

The purpose of the Infant Formulas – Ingredients and Indications is to provide health professionals with information on ingredients and indications for the use of infant formulas available at the retail level and is intended for professional reference only when advising those who cannot or have made an informed decision not to breastfeed or to partially breastfeed.

This document was developed by the Public Health Nutrition 0-6 Working Group.

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Companion Documents

For All Health Professionals – Infant Formulas – Summary Sheet

A summary sheet that lists infant formulas for retail sale in Canada by category is available for health professional use: Infant Formulas – Summary Sheet | Alberta Health Services

Alberta Health Services (AHS) does not endorse or recommend one specific commercial infant formula over another unless it is intended to meet a specific clinical need.

For AHS Health Professionals – Infant and Pediatric Formula Compendium

Infant formula nutrient composition, including sources of protein, fat and carbohydrate, is available for AHS health care professional use on Insite in the Infant & Pediatric Formula Compendium. For more information about infant formulas used in AHS, visit the Enteral Nutrition Insite page.

Definitions

Casein: the insoluble component of cow's milk protein, comprising 80% of the milk protein fraction.[1]

Colic: recurrent and prolonged periods of infant crying, fussing, or irritability reported by caregivers that occur without obvious cause and cannot be prevented or resolved by caregivers.[2] There is no evidence of infant failure to thrive, fever, or illness.[2] Symptoms start and stop in infants less than five months of age.[2] "Fussing" refers to intermittent distressed vocalization and has been defined as "[behaviour] that is not quite crying but not awake and content either." Infants often fluctuate between crying and fussing, so the two symptoms are difficult to distinguish in practice.[2]

Docosahexaenoic acid (DHA) and arachidonic acid (ARA): long-chain polyunsaturated fatty acids that have a role in brain and retina development.[3] DHA is an omega-3 fatty acid.[3] ARA is an omega-6 fatty acid.[3]

Food allergy: a medical condition where the immune system mistakenly treats something in a particular food (most often, the protein) as if it is dangerous. The body reacts to the allergen by triggering an allergic reaction.[4]

Galactosemia: a rare inborn metabolic disorder of carbohydrate metabolism characterized by the inability to metabolize galactose and resulting in life-threatening symptoms if galactose is not restricted in the diet.[5] Dietary galactose is mainly found in breastmilk and dairy products in the form of lactose, a disaccharide formed by glucose and galactose.[5]

Gastroesophageal reflux: the passage of gastric contents into the esophagus, with or without regurgitation ("spitting up").[3]

Inclusive language terms: some clients may not identify with the term breastmilk and/or breastfeeding, and may instead identify with terms such as chestmilk or human milk, and/or chestfeeding, body feeding,[6] or nursing. In all circumstances, care providers shall utilize client- and family-centred care to be responsive to the self-identified gender, pronouns, and terminology of the families they support.[6]

Infant formula: throughout the document, the words “infant formula” and “formula” refer to commercial infant formula. Infant formula is a substitute for human milk that is given to infants typically during the first year of life.[7]

Lactose intolerance: lactose malabsorption with associated gastrointestinal symptoms.[8] Symptoms in infants, which generally occur within 30–60 minutes of ingesting lactose-containing foods, include diarrhea, perianal skin irritation, excoriation, and abdominal pain and distension.[8] The four main clinical types of lactose intolerance are:[8]

- **developmental lactase deficiency**: observed in premature infants (less than 34 weeks gestation) due to temporary lactase deficiency which improves with time.
- **congenital lactase deficiency**: a rare and severe autosomal recessive disorder caused by low or absent small intestinal lactase. Presents with severe watery diarrhea at the commencement of breastfeeding or lactose-containing infant formula.[8]
- **lactase non-persistence**: physiological gradual decline of lactase activity after weaning. Significant gastrointestinal symptoms generally do not occur before five years of age. [8]
- **secondary lactose intolerance**: May occur as a consequence of small bowel injury due to conditions such as viral gastroenteritis, celiac disease, or Crohn’s disease. Infants with glucose-galactose malabsorption have normal lactase activity but present with osmotic diarrhea due to the inability to absorb glucose and galactose (derived from lactose).[8]

MCTs (medium-chain triglycerides): saturated fatty acids with carbon chain lengths of 6–10 atoms which are more easily hydrolyzed, better absorbed, and more rapidly oxidized than long-chain triglycerides.[9]

Nucleotides: non-protein nitrogenous compounds which are precursors of nucleic acids and a component of coenzymes.[10]

Parent/caregiver: the term 'parent' will be used throughout this document to indicate parents, caregivers, or other persons caring for a child in the context of the family unit.

Partially hydrolyzed protein formula: infant formula in which the cow's milk protein has been broken down into components or peptides that are smaller than the intact protein, but larger than the end products in extensively hydrolyzed protein formula.[11]

Prebiotic: a substrate that is selectively utilized by host microorganisms conferring a health benefit.[12]

Probiotics: live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.[13]

Regurgitation (spitting up): the passive movement of stomach contents into the pharynx or mouth.[14]

Whey: the soluble component of cow's milk protein, comprising 20% of the milk protein fraction.[1]

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Introduction

This document provides information on ingredients and indications for the use of infant formulas available at the retail level and is intended for professional reference only when advising those who cannot or have made an informed decision not to breastfeed or to partially breastfeed.

This document was prepared with the full recognition that breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants.[15] Exclusive breastfeeding for the first six months, and continued for up to two years or longer, is recommended for the healthy growth and development of infants and toddlers.[3] and for the benefits to the individual who is lactating.[16] As per the AHS Breastfeeding Policy[17] health professionals must support parents/caregivers and their families to make informed feeding decisions.

If an infant is not fed breastmilk or is partially fed breastmilk, infant formula sold in Canada will meet the nutrition needs of infants and is the only recommended breastmilk substitute for infants.[18] Infant formula is available in three formats: ready-to-serve liquid, concentrate that must be diluted with water, or powder that is to be mixed with water.[7] Parents are advised to follow AHS guidelines for preparing infant formula and to follow the manufacturer's instructions (on the formula label) for the amount of infant formula and water to use. Health professionals should refer to the Nutrition Guideline: Safe Preparation and Handling of Infant Formula.

Canadian Regulations for Infant Formula

Infant formula is regulated under the Food and Drug Regulations.[19] Before an infant formula can be sold or advertised for sale in Canada, Health Canada assesses whether the infant formula is safe and nutritionally adequate to promote acceptable growth and development in infants.[20] All manufacturers, importers, and distributors of infant formula are responsible for ensuring their products comply with Canadian legislation.[18,21]

Some infant formulas are eligible for some health insurance coverage or Income Support programs (e.g. extensively hydrolyzed casein formulas).

For more information on infant formula labelling, safety, and recalls refer to Health Canada Food and Nutrition.

Interim Policy on the Importation and Sale of Infant Formulas

Starting in 2022, Health Canada allowed the temporary importation and sale of certain infant formulas to mitigate infant formula shortages.[21] These products have been reviewed and approved for sale in Canada. The Health Canada Interim Policy and a list of approved formulas are available for more information: Interim Policy and List of Approved Formulas | Health Canada.

Caution Regarding Infant Formula Purchased Outside of Canada

It is not recommended to purchase infant formula online from another country as these products are not reviewed and approved by Health Canada. Therefore, it is not known if these infant formulas meet Canadian standards for safety and nutritional content. Other potential risks of purchasing infant formula online from another country include:

- Nutrient oxidation when infant formula powder is stored at high temperatures. Long-chain polyunsaturated fatty acids in powdered infant formula are sensitive to oxidation when stored at temperatures of 55°C and must be stored at proper temperatures to ensure their safety and quality.[22]
- Labels and instructions that are in another language (not English or French) create a risk if formula preparation and storage cannot be followed. In addition, there is no system in place to report infant formula recalls for formula purchased outside of Canada.

For more information:

- Online Shopping: Product Safety | Health Canada
- Online shopping | Government of Canada
- Product Certification & Standards Development | CSA Group

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Stage 1 and Stage 2 Infant Formulas

Stage 1 and stage 2 infant formulas both function as partial or total replacements for breastmilk.[23]

Stage 1 Infant Formulas

In Canada, term infant formulas are designed to be nutritionally adequate for term infants from birth to 12 months of age.[24] These formulas are typically labelled as stage 1, step 1, or simply with the number '1', and may also be referred to as 'starter' or 'routine' formulas.[25–27]

Stage 2 Infant Formulas

Infant formulas designed for infants six months of age or older are known as follow-up formulas[28] and are labelled as stage 2, step 2, or with a number '2'.[29–31] These formulas are cow's milk-based, and while similar to stage 1 infant formulas in terms of energy, fat, and carbohydrate, they have higher amounts of calcium and phosphorus.[26,27,29–32] Even though calcium and phosphorus needs increase in the second six months of life,[33] switching from a stage 1 to a stage 2 infant formula offers no advantage for infants receiving sufficient amounts of calcium and phosphorus from complementary foods.[34] Stage 2 formulas are not suitable for infants younger than six months of age.[35]

Stage 3 Beverages (Toddler Supplements)

Stage 3 beverages, also known as young child formulas or toddler drinks, are labelled as toddler nutritional supplements in Canada*.[34,36–38] Products currently available in Canada include Enfagrow® A+, Go and Grow by Similac®, Good Grow™, NIDO®, and Else™ Toddler†.[36–40] These products are not the same as stage 1 or stage 2 infant formulas and are inappropriate for infants under 12 months of age. [36–40] They are marketed for young children aged 12 to 36 months as a substitute or supplement to cow's milk[36–40] and are also considered breastmilk substitutes.[41]

After 9–12 months of age, toddlers should be eating a variety of complementary foods and can transition directly to 3.25% milk, which serves as a partial or complete replacement for breastmilk.[28]

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* The Food and Drug Regulations define "nutritional supplement" as a food sold or represented as a supplement to a diet that may be inadequate in energy and essential nutrients. Refer to the Regulations Amending the Food and Drug Regulations (Human Milk Fortifiers) | Canada Gazette for more information.

† Stage 3 toddler supplements are not included in the companion document Infant Formulas – Summary Sheet.

For most healthy young children older than 12 month months, there is no indication for the use of infant formulas or toddler supplements if they are receiving sufficient amounts of vitamins and minerals through complementary foods.[34] Possible disadvantages of the use of toddler supplements are continued preference for liquid foods and subsequently reduced interest in complementary foods that require chewing.[34] The availability of such products may suggest to parents that these manufactured supplement beverages are a safer and healthier alternative for meeting a child's nutritional requirements, rather than transitioning to family foods.[34] The use of toddler supplements instead of 3.25% cow's milk may also create a financial burden on families.[34] At the time of writing, toddler supplements in Alberta cost at least two‡ to three times§ as much per mL than 3.25% cow's milk.

Since toddler supplements contain more iron and DHA than 3.25% milk, they may have benefits for some children not obtaining enough of these nutrients from food. If parents provide a toddler supplement due to nutrition concerns, it is recommended to consult a dietitian regarding these nutrition concerns.

Indications for Type of Infant Formula

Standard Cow's Milk Formulas

Standard cow's milk-based infant formulas are designed to resemble the nutrient composition of human milk.[10] Standard formulas in this document and the Infant Formulas – Summary Sheet refer to those with intact cow's milk protein[42] and unaltered lactose content. Standard intact cow's milk protein formulas are recommended for formula-fed healthy term infants until 9–12 months of age, regardless of their risk of allergy.[43] Standard formulas are not suitable for infants with cow's milk protein allergy, galactosemia, or for those who cannot consume dairy-based products for religious[3] or personal reasons.

Standard cow's milk formulas may contain added nutritive substances (e.g., DHA and/or prebiotics) that are not required under the Food and Drug Regulations.[3] These optional ingredients are discussed later in this document.

‡ Calculations based on Walmart.ca prices of Good Grow 850 g powder, reconstituted, and regular 3.25% cow's milk, 1 L carton

§ Calculations based on Walmart.ca prices of Enfagrow A+ 6 x 237 mL, ready-to-drink, and regular 3.25% cow's milk, 4 L carton

Modified Cow's Milk Formulas

Partially Hydrolyzed Protein Formulas

Partially hydrolyzed protein infant formulas contain either partially hydrolyzed whey or a combination of partially hydrolyzed whey and casein protein.[27,44–47] Some also have reduced lactose levels[44–47] (see Lactose-Reduced Formulas below for more information). Partially hydrolyzed protein formulas are considered safe and lead to appropriate infant growth.[11] However, there is little evidence to support any benefit of a partially hydrolyzed protein formula compared to standard cow's milk protein formula[3] despite the health benefits implied[48,49] by these formula names (e.g., "soothe", "comfort", "gentle" and "serenity") and claims (e.g., comfort proteins™, easy to digest,[45–47] tummy-friendly,[45,46] for fussiness,[44,45] tummy troubles,[46] or sensitive tummies[44]). The reported benefits of using partially hydrolyzed formulas for reducing colic are inconsistent and the quality of evidence is very low.[48] Current evidence does **not** support feeding a partially hydrolyzed formula compared with exclusive breastfeeding or a standard cow's milk formula for the prevention of allergic disease, whether or not an infant is at high risk or low risk of allergic disease.[50] Refer to Practice Change Notice Hydrolyzed Formulas and Allergy Prevention for more information.

Lactose-Reduced Formulas

Lactose-reduced formulas contain 20–70% of the lactose levels of routine cow's milk-based formulas: Good Start Soothe™: 70% lactose;[44] Enfamil A+® Gentlease®: 20% lactose;[46] Enfamil A+® Serenity™: 50% lactose.[47] The lactose content of Similac Total Comfort® is unclear; it does not contain added lactose but does not claim to be lactose-free by the manufacturer.[45] There is no clear indication for the use of lactose-reduced formulas.

Lactose-Free Formulas

Glucose polymers, usually from corn syrup solids, replace lactose in lactose-free cow's milk-based infant formulas.[3] However, these formulas still contain a small amount of residual lactose and are therefore not suitable for infants with congenital lactase deficiency or galactosemia.[3] Lactose-free infant formulas are also not suitable for infants with cow's milk protein allergy[3] and are thought to be ineffective in the dietary management of infant colic.[8] During episodes of acute diarrhea, temporarily switching formula-fed infants to a lactose-free formula may reduce diarrhea duration.[51]

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Soy Formulas

There are limited indications for feeding soy formulas to term infants. These indications include the management of infants with galactosemia or primary lactase deficiency and infants who cannot consume dairy-based products for religious or personal reasons, such as a vegetarian lifestyle.[3,52,53]

Note: The vitamin D in soy formula available in Canada is obtained from sheep's wool lanolin without causing harm to the animal. This may be acceptable to some families following a vegan or plant-based diet and is therefore important to share with them.[52]

Soy infant formulas contain phytoestrogens called isoflavones[52] which are non-steroidal chemicals that are structurally similar to estrogens.[56] Some studies found that most of the phytoestrogens present in soy infant formula are in a conjugated form, and therefore, are unable to exert hormonal effects.[57] However, further research is warranted, and the use of soy infant formulas should be limited to the indications described above.

The use of soy infant formulas is not appropriate for infants:

- with soy protein allergy.
- with non-IgE-mediated cow's milk protein allergy (CMPA) due to the high rate of coincident soy allergies.[52] The use of soy formula is an acceptable alternative if a non-IgE-mediated CMPA can be satisfactorily ruled out as the coincident soy allergy for IgE-mediated CMPA is much less frequent.[3,52,53] It is usually safer and more appropriate to recommend an extensively hydrolyzed casein formula for infants with CMPA, especially in infants younger than six months of age.[52] Guidance from a physician is recommended to help determine when using a soy formula for children with CMPA is appropriate.[58]
- born preterm. Soy formulas have high aluminum content and aluminum toxicity may develop in preterm infants due to their reduced renal function.[57] As aluminum competes with calcium for absorption, this may result in reduced skeletal mineralization (osteopenia).[57] Serum phosphorus concentrations are lower and alkaline phosphatase concentrations are higher in preterm infants and infants with intrauterine growth restriction (IUGR) fed soy infant formula, compared to preterm infants fed cow's milk infant formula. Therefore, the degree of osteopenia is increased in infants with low birth weight receiving soy infant formulas.[53]
- with congenital hypothyroidism**.** Infants with congenital hypothyroidism fed soy infant formula need close monitoring due to reported abnormal thyroid function. This does not appear to be a concern in infants with healthy thyroid function.[58]

Formulas for Use Under Medical Supervision

Post-Discharge Preterm Formulas

Post-discharge preterm formulas have been specifically designed to meet the needs of preterm and low-birth-weight infants after discharge from the hospital and should only be used with the advice of a physician or dietitian. For more information on these infant formulas refer to the Nutrition Guideline: Post-discharge Preterm Formula.

Gastroesophageal Reflux (GER)–Infant Formulas for Spit-Up

Regurgitation (spitting up) is normal in infancy and only rarely leads to health problems such as growth faltering.[3] In infants, regurgitation reflects physiological immaturity,[3] usually improves without any medical intervention,[59,60] becomes less frequent with time, and resolves in 90% of infants before one year of age.[61] Further assessment is needed if regurgitation persists or increases in severity.[3] As a cow's milk protein allergy is sometimes a cause of vomiting in infants, formula-fed infants with recurrent regurgitation and vomiting may benefit from a two- to four-week trial of an extensively hydrolyzed formula under medical supervision.[62]

Gastroesophageal reflux (GER), with or without regurgitation, is relatively common in healthy-term infants with regurgitation occurring daily in approximately 50% of infants three to four months of age.[3] Education on feeding changes,[60] anticipatory guidance, and support are usually sufficient to manage healthy, thriving infants with symptoms resulting from physiologic GER.[60,62]

Formula that thickens in an infant's stomach is intended for infants with mild GER and should be used only when recommended by a physician. Thickened infant formula does not decrease the frequency of reflux episodes but may decrease visible regurgitation which may improve quality of life for parents/caregivers.[62] This type of infant formula is not intended for infants who need specialized thickened formula due to swallowing difficulties. It is not recommended to thicken infant formula with infant cereal[3] as this may increase coughing during feeding, impair absorption of nutrients, lead to excessive weight gain, or increase gastrointestinal symptoms.[60]

Extensively Hydrolyzed Formulas

Extensively hydrolyzed casein infant formulas contain protein from cow's milk that has been heat-treated for hydrolysis and/or enzymatically hydrolyzed into short-chain peptides and amino acids.[10] Casein was the protein source in extensively hydrolyzed formulas in Canada[3] until the importation of extensively hydrolyzed whey protein and extensively hydrolyzed rice protein formulas were allowed as part of Health Canada's interim policy to manage infant formula shortages.[21]

A cow's milk-derived extensively hydrolyzed formula (casein or whey) is recommended as the first choice for formula-fed infants with:

- suspected cow's milk protein allergy who are on a diagnostic elimination diet.[63]
- diagnosed cow's milk protein or soy protein allergies.[3,63–66]
- specific malabsorption syndromes.[3,65,66]

Hydrolyzed rice formulas are an alternative to extensively hydrolyzed casein formulas for the management of cow's milk allergy. However, hydrolyzed rice formulas have not been evaluated for safety and nutrition in the same way as cow's milk-based extensively hydrolyzed formulas, and therefore, more RCTs studying hydrolyzed rice formulas are recommended.[63]

Extensively hydrolyzed formulas are not indicated for allergy prevention.[43] Refer to Practice Change Notice Hydrolyzed Formulas and Allergy Prevention for more information.

Amino Acid-Based Formulas

Amino acid-based infant formulas, also known as elemental formulas, contain 100% free synthetic amino acids and have a lack of proteic residual allergenicity as they are not derived from cow's milk protein.[10,67] Amino acid-based formulas are more expensive than extensively hydrolyzed formulas and have poor palatability when not started at a young age.

An amino acid-based formula is recommended as the first choice for formula-fed infants with:

- anaphylaxis to cow's milk protein[67]
- cow's milk protein allergy associated with multiple food allergies[67] or faltering growth[63]
- allergies who do not respond to extensively hydrolyzed formulas[3,63]
- eosinophilic esophagitis who do not respond to extensive food-elimination diets or who are not yet eating complementary foods[67]
- acute or chronic severe cow's milk protein-induced enterocolitis syndrome[67]

Indications for Certain Infant Formula Ingredients

Iron

In Canada, all retail infant formulas are required to contain iron in amounts that meet the iron requirements of term infants.[24] Therefore, it is unnecessary to recommend an 'iron-fortified' infant formula to clients since all formulas, including those labelled as 'low iron', are adequate in iron.[24,68] A review of product labels shows the iron content in retail infant formulas currently ranges from 6.5 to 13 mg/L.

Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA)

DHA and ARA are not required to be added to infant formula in Canada but are permitted.[3,69] Health Canada has not specified levels of DHA and ARA to be added to the formula.[70] DHA and ARA are found naturally in breastmilk and are essential for the maturation of the developing brain, retina, and other organs in newborn infants.[71] DHA and ARA can be synthesized from their precursors alpha-linolenic acid and linoleic acid, respectively;[71] however, researchers have questioned if formulas containing only alpha-linolenic and linoleic acid are effective in meeting the full essential fatty acid requirements of infants.[71] Based on the most recent Cochrane review,[71] there are no consistent beneficial effects for term infants of DHA- and ARA-supplemented formula on visual acuity, neurodevelopmental or physical growth.[71] Even though some studies reported potential benefits, and formulas with added DHA and ARA are marketed as providing an advantage for infant development,[71] recommending formulas with added DHA and ARA presents a problem of inequity since these formulas currently cost more than the same infant formula without added DHA and ARA.[49] The evidence is not strong nor consistent enough to make a public health recommendation for routine use of DHA- and ARA-supplemented formula for formula-fed term infants.[71]

The most recent Cochrane review of formula-fed preterm infants receiving formula with added DHA and ARA also showed no clear long-term benefits or harms, although the overall quality of evidence was low.[72]

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Nucleotides

Nucleotides are not required to be added to infant formulas in Canada but are permitted.[3,69] Nucleotides are considered to be conditionally essential, which means that they are not typically needed from the diet because humans possess the biological pathways to synthesize the nutrient, but under conditions like rapid growth or illness dietary intake of the nutrient may optimize tissue function.[73] Nucleotides are found in higher concentrations in breastmilk than in cow's milk[74] and therefore some manufacturers add nucleotides to infant formula in an attempt to mimic the composition of breastmilk. Nucleotides have a role in modulating immune function, plasma fatty acid composition, and promoting intestinal development.[74] Some studies report an association between nucleotides in infant formulas and increased head growth and rate of early weight gain, however, the benefits of using an infant formula with added nucleotides are still inconclusive.[74] For this reason, and because there are no recommendations by the Food and Drug Regulations or consensus from international experts as to the type or amount that should be added,[7] a recommendation to choose an infant formula with added nucleotides cannot be made at this time.

Prebiotics

Prebiotics studied for use in infant formula and on the Canadian market are galactooligosaccharides (GOS), polydextrose (PDX), fructooligosaccharides (FOS), 2'-fucosyllactose (2'-FL), a human milk oligosaccharide (HMO), as well as combinations of these.[75–78] HMOs that are naturally present in breastmilk have been studied for their benefits to the immune system including anti-bacterial, anti-viral, and anti-inflammatory effects.[78] Evidence to support this claim in infant formulas continues to emerge.[79]

Probiotics

Bifidobacterium lactis BB-12 (*B. lactis*),[80] *Lacticaseibacillus* (formerly *Lactobacillus*) *rhamnosus* GG (LGG),[64] and *Lactobacillus reuteri DSM 17938* (aka *Limosilactobacillus reuteri*) *(L. reuteri)*[44] are probiotics currently added to some infant formulas in Canada. Further studies with larger sample sizes, testing dose, strain,[81] duration, and timing[76] are required before it can be recommended that probiotic cultures be needed in infant formula.[82] Because new evidence continues to emerge and available probiotic products frequently change, health professionals can consult probioticchart.ca for current evidence-based indications for using formulas with added probiotics.

For more information refer to the Nutrition Guideline: Prebiotics and Probiotics.

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