



Concerns for the use of soy-based formulas in infant nutrition

In 1998, a Joint Working Group statement was published, titled “Nutrition for Healthy Term Infants” (1) and authored by the Canadian Paediatric Society, Dietitians of Canada and Health Canada. In the statement, breastfeeding was recognized as the optimal method for feeding infants. As part of the statement, the use of soy-based formulas was recommended for only those infants who could not have dairy-based products because of health, cultural or religious reasons, such as a vegan lifestyle or due to galactosemia (1). At the time of the statement’s release, utilization rates of soy-based formula were up to 20% among infants in Canada, which were far greater than could be accounted for by the aforementioned reasons. The high utilization rates were presumably because of the ongoing use of soy-based formulas due to perceived or real allergy to cow’s milk protein (CMP) (1), and perhaps due to the lack of lactose-free CMP formulas, of which there are now plenty.

Also briefly discussed in the “Nutrition for Healthy Term Infants” statement was the subject of phytoestrogens, which are a component of soy-based formulas. Over the past several years, the potential harms and benefits of phytoestrogens have been raised in the media and medical literature, sparking concern about the short- and long-term implications for infants who have been exposed to them through consumption of soy-based infant formulas as their sole source of nutrition.

Therefore, the purpose of the present practice point is twofold. First, to provide an update on what has been learned about phytoestrogens and the implications of their presence in soy-based infant formulas. Second, to revisit the recommendations regarding the use of soy-based formulas, particularly as they apply to the treatment of infants with CMP allergy (CMPA).

PHYTOESTROGENS – WHAT ARE THEY AND SHOULD WE BE CONCERNED ABOUT THEIR PRESENCE IN SOY-BASED INFANT FORMULAS?

Although at present there is no definitive evidence that phytoestrogens have toxic effects in human infants who are fed a diet of soy formula, concern has been raised from research carried out *in vitro* and in animal studies. The present practice point seeks to provide an overview of phytoestrogens and soy formulas. More detailed information on phytoestrogens and human health is available through several excellent expert panel reviews (2,3) on the subject. In reviewing this topic, it is important to be

clear on soy nomenclature. Some of the confusion in interpreting the literature on soy is the varied forms in which this product can be consumed. It ranges from whole soy foods evaluated in epidemiological studies to components of soy, such as soy concentrates, soy isolates, isolated isoflavone mixtures, supplements or pure isoflavones (4).

Phytoestrogens are plant-derived substances with estrogenic activity. Soy-based infant formulas contain phytoestrogens of the isoflavone class, which includes genistein, daidzein and glycitein. These isoflavones are relatively weak estrogens, with approximately 1/1000 to 1/10,000 of the potency of estradiol in the rodent uterotrophic assay – the ‘gold standard’ for determining estrogenic activity in experimental animals (5,6). However, they are present in relatively large amounts in soy-based formulas, such that the total isoflavone content is approximately 40 µg/mL in ready-to-use soy formulas. Infants who consume these products have isoflavone plasma concentrations of approximately 13,000 to 22,000 times greater than their estradiol plasma concentrations. In contrast, the plasma concentrations of isoflavones in infants who are fed cow’s milk formula or breast milk are only 50 to 200 times greater than their estradiol plasma concentrations (7). There is concern that these isoflavones may mimic the actions of estradiol or alter estradiol metabolism, and consequently modify the processes influenced by estradiol. Despite this theoretical possibility, practical experience has shown that the millions of infants who have consumed these products since the 1960s appear to have grown and matured normally.

The daily intake of phytoestrogens by infants consuming soy-based formula ranges from 4 mg/kg to 11 mg/kg body weight (7). This dose is greater than the daily intake of approximately 1 mg/kg body weight of an adult consuming a traditional Japanese diet or a person consuming a modest amount of soy products (8). Over 94% of the phytoestrogens in soy-based infant formulas are present in a biologically inactive form, primarily as beta-glycosylated isoflavones (7). Once ingested, phytoestrogens are activated by the removal of glycoside by bacteria in the intestinal tract – a process necessary for absorption (9). Data from animal studies (10) suggest that phytoestrogens may be transformed into an inactive glucuronidated form during the absorption process, or once absorbed, they may be inactivated by the liver through the formation of glucuronidated or sulfated isoflavones. Whichever the case, clinical data show that 0% to 3% of

the phytoestrogens present in the plasma of infants who consume soy-based formula are in the biologically active form (11). Infants that are fed soy-based formulas do not accumulate phytoestrogens in their plasma (12).

Although no overt toxicity is associated with the consumption of soy-based infant formula in healthy infants (13), a recent clinical study (14) has reported the development of abnormal thyroid function from the ingestion of soy-based formula in infants with congenital hypothyroidism. Data from animal studies (15) suggest that phytoestrogens can inhibit thyroid peroxidase, potentially lowering free thyroxine concentrations, which could lead to abnormal thyroid function. Therefore, infants with congenital hypothyroidism who are fed soy-based infant formulas should have their thyroxine levels monitored. This does not appear to be a problem in infants with healthy thyroid function.

The results of the animal experiments are often not applicable to the human infant because they involve exposing animals for relatively longer periods of time than humans, treating animals with higher doses than human exposure, administering phytoestrogen by routes not relevant to the human situation or a combination of these factors. Other animal studies (16-18) have shown no significant physiological effects under more applicable conditions. Although the neonatal rodent is a useful model for exploring potential toxicities, it is not equivalent to the human newborn in terms of developmental stages (19); therefore, results from this model should only be applied to the human infant with caution. Animal studies (7,20-23) have shown that consumption of phytoestrogens can result in infertility. Furthermore, exposure of neonatal animals to the isoflavones present in soy-based formula can cause subtle alterations in sex organ development (24-26), brain maturation (27) and immune system function (28), and can also stimulate cancer development (29). Although these results highlight areas of concern that require further study, the direct extrapolation of these findings to human infants is problematic for a number of reasons (3,4).

A recent retrospective human study (30) showed that adults who consumed soy-based formulas as infants were not different from adults who had been fed cow's milk-based formulas with respect to reproductive maturity, cancer development and general health. No statistically significant differences were found between the two adult male groups. Women fed soy-based formulas as infants had a slightly greater incidence of regularly using asthma and allergy medications than the group who were fed cow's milk formulas ($P=0.047$). Also, women who were fed soy-based infant formulas had a slightly longer duration of menstrual bleeding (0.37 days) and experienced more discomfort during their menstruation than the group who were fed cow's milk formulas. The authors of the study did not consider these findings to be biologically significant, but others had concerns about the potential implications of these findings (31).

Currently available soy-based formulas support normal growth and nutritional status for the first year of life, with no overt toxicities observed in normal infants (3,32-37). However, soy-based infant formulas may not adequately promote growth in premature infants, and its use in this population is not recommended (3,38). Long-term safety data are very limited, but no significant toxicities have been reported (30). In addition to these studies, over 40 years of use support the safety of currently available formulations (39). The Committee on Toxicity (United Kingdom) released a report in 2003 titled "Phytoestrogens and Health" (2), which identified infants who were fed soy-based formulas as the population subgroup with exposure to the highest concentrations of isoflavones. Although this committee did not identify definitive evidence of adverse health effects in their review, they believed that the potential risks were a concern. The Committee on Toxicity also sought consultation with the United Kingdom's Scientific Advisory Committee on Nutrition, who suggested that there was no substantive medical need for, nor health benefit arising from, the use of soy-based infant formulas.

THE ROLE OF SOY-BASED FORMULAS IN CMPA

There is no argument that CMPA is the most common food allergy experienced by infants. Prospective studies (40-43) have demonstrated a CMPA incidence of approximately 2.5% among infants younger than one year of age. However, making a definitive diagnosis of CMPA can be difficult. Infants are most commonly diagnosed with CMPA based on clinical symptoms, signs and laboratory findings. Despite the recommendations made in the "Nutrition for Healthy Term Infants" statement, soy-based formulas, rather than extensively hydrolyzed formulas, are frequently selected for many of these infants. The chief reasons for selecting the soy-based formulas are their reduced cost when compared with the hydrolyzed formulas and their superior palatability (44). Although published Canadian data on reasons for selecting soy-based formula are lacking, a recent Israeli study (45) provided some potentially applicable insights. Using a telephone survey of mothers attending well-baby clinics, the researchers showed that the role of the mothers in the decision to use soy-based formulas was greater than that of the medical personnel. Interestingly, a suspicion of CMPA was responsible for approximately only 10% of all soy initiations in the infants studied. The researchers reported that medical personnel most commonly recommended soy-based formula for occasional symptoms such as diarrhea or colic, while personal preference without clinical justification was the main reason stated among mothers (45).

A number of paediatric societies have published recommendations on the use of soy-based formula in children, frequently with discussions of its role in the management of CMPA. With respect to its use in CMPA, the use of soy-based formulas is only contraindicated for nonimmunoglobulin E (IgE)-mediated CMPA (46). This contraindication stems from the high rate of coincident soy allergies in these

patients. It is clear that in patients with a documented IgE-mediated CMPA, coincident soy allergy is much less frequent (range 7% to 14%) (44,47,48). The differential risk of concomitant soy allergy between patients with IgE- and non-IgE-mediated CMPA was drawn into question by results from a recent study by Klemola et al (44). They failed to demonstrate a significant difference in the number of adverse reactions for infants with CMPA who were randomly assigned to receive a soy-based formula versus an extensively hydrolyzed formula. However, their results need to be viewed with the possibility that a referral bias existed in that the authors were allergists (and thus more likely to see IgE-mediated CMPA), and that the patients at study entry were generally older than those typically seen with non-IgE-mediated type CMPA – all which may limit the applicability of their results to the non-IgE-mediated CMPA population. Pending confirmation of the Klemola et al (44) findings by other groups, the risk of adverse reaction remains a concern if soy-based formulas were to be used in the case of non-IgE-mediated CMPA.

Both the American Academy of Pediatrics and the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) Committee on Nutrition recently produced papers on soy protein infant formulas (38,49). They recommend extensively hydrolyzed protein (or amino acid-based formulas if hydrolyzed formulas not tolerated) for the treatment of infants with CMPA. The ESPGHAN Committee on Nutrition also specified that especially for infants younger than six months of age, soy-based formulas should not be used to treat CMPA given the higher reported rate of adverse reactions to soy protein in the population (38). This committee also recommended that before soy-based formulas are selected in older infants, tolerance to soy protein should first be established by clinical challenge (38). Likewise, the Australian position statement (50) clearly advocates for the strict avoidance of soy-based formulas in infants with CMPA. The United Kingdom and New Zealand recommendations, separately, have more strongly recommended against the use of soy-based formula for any indication, citing concerns about the unknown risk of phytoestrogens when infants are receiving the formulas as the sole source of nutrition (2,51).

Some of the limitations to the studies on CMPA have been the lack of uniformity in what is labelled or diagnosed as CMPA, and the failure to distinguish between IgE- and non-IgE-mediated CMPA. (For the purposes of the present paper, two broad types of CMPA are described – IgE- and non-IgE-mediated. The authors recognize that this classification is a simplified version and does not represent a true breakdown of the various classifications of hypersensitivity reactions). In part, this has led to some apparently contradictory or unclear recommendations for the treatment of CMPA. Symptoms and signs alone have been used to make the diagnosis, but these lack appropriate sensitivity and specificity for distinguishing between IgE- and non-IgE-mediated CMPA. Traditionally an IgE-mediated CMPA would present with urticaria, angioedema, respiratory and gastrointestinal

features. In contrast, non-IgE-mediated CMPA presents with significant gastrointestinal manifestations, most frequently with blood in the stool. However, the boundary between the symptoms and signs of IgE- and non-IgE-mediated CMPA is not distinct. Skin prick testing or detection of either specific or nonspecific IgE antibodies can be helpful in the diagnosis of IgE-mediated allergies if they are positive (52).

These tests function poorly in non-IgE-mediated allergies (52). The gold standard for the diagnosis of CMPA is the double-blind, placebo-controlled food challenge (53). This procedure has been shown to be both sensitive and specific for the diagnosis of food allergy, but can be cumbersome and difficult to use in practice, especially in the context of a clinical trial. Another limitation of many studies on CMPA is the age of the infants at baseline. Most studies have investigated infants who are older than six months of age at presentation; however, for non-IgE-mediated CMPA, the clinical presentation is usually before six months of age. Because many of the studies have not examined patients in this age group, it limits the applicability of the results to the non-IgE-mediated CMPA population. In addition, prospective data on the comparative incidence of the two types of CMPA are limited. Many researchers either have poorly defined CMPA, or have not distinguished between the two types of CMPA. It would appear that IgE-mediated CMPA may be more frequent than non-IgE-mediated CMPA, with 60% to 40% breakdown, respectively (40).

The problem, however, is that in most circumstances it will be the primary care physician who will be making the differentiation. It is often difficult to make the distinction between IgE- and non-IgE-mediated CMPA. If available, consultation with an allergist to make the distinction between IgE- and non-IgE-mediated CMPA would be very helpful. On a population level, the latter approach may not always be possible. Therefore, the safer route is to recommend the use of extensively hydrolyzed infant formula when a diagnosis of CMPA is made, with the caveat that if non-IgE-mediated CMPA can be satisfactorily ruled out, then the use of soy formula is not contraindicated.

IMPLICATIONS FOR PRACTICE

Breastfeeding remains the first choice for infant feeding. There are concerns based on animal and *in vitro* data regarding the phytoestrogen content of soy-based formulas, and the potential risks for those infants who receive their sole sources of nutrition from these formulas. However, based on available human data, no overt harm has been proven with the use of currently available soy-based infant formulas as the sole source of nutrition for infants. An exception to this remains the use of soy-based formulas in premature infants or infants with congenital hypothyroidism. In clinical practice, a perceived indication by clinicians for the initiation of soy-based formula is CMPA. Although not all CMPA requires protein hydrolysate formulas, given the impractical nature of distinguishing IgE- versus non-IgE-mediated CMPA, it is safer and

more appropriate from a public health standpoint to recommend a protein hydrolysate formula.

Cost has been identified as a barrier to the use of protein hydrolysate formulas. Given the limited indications for the use of soy-based formulas, there is a role for physicians: to counsel families about breastfeeding, to inform families about alternative formulas, and to advocate on the behalf of families to the government for assisted coverage of protein hydrolysate formulas when used to treat CMPA.

REFERENCES

- Canadian Paediatric Society, Dietitians of Canada, Health Canada. Nutrition for Healthy Term Infants. Minister of Public Works and Government Services, Ottawa, 2005.
- Committee on Toxicity of Chemicals in Food. COT Report – Phytoestrogens and Health. Consumer Products and the Environment, Food Standards Agency, Department of Health, United Kingdom, 2003.
- Rozman KK, Bhatia J, Calafat AM, et al. NTP-CERHR expert panel report on the reproductive and developmental toxicity of soy formula. *Birth Defects Res B Dev Reprod Toxicol* 2006;77:280-397.
- Erdman JW Jr, Badger TM, Lampe JW, Setchell KD, Messina M. Not all soy products are created equal: Caution needed in interpretation of research results. *J Nutr* 2004;134:1229S-33S.
- Shutt D. The effects of plant oestrogens on animal reproduction. *Endeavour* 1976;35:110-3.
- Song TT, Hendrich S, Murphy PA. Estrogenic activity of glycitein, a soy isoflavone. *J Agric Food Chem* 1999;47:1607-10.
- Setchell KD, Zimmer-Nechemias L, Cai J, Heubi JE. Exposure of infants to phyto-oestrogens from soy-based infant formula. *Lancet* 1997;350:23-7.
- Nagata C, Takatsuka N, Kurisu Y, Shimizu H. Decreased serum total cholesterol concentration is associated with high intake of soy products in Japanese men and women. *J Nutr* 1998;128:209-13.
- Setchell KD, Brown NM, Zimmer-Nechemias L. Evidence for lack of absorption of soy isoflavone glycosides in humans, supporting the crucial role of intestinal metabolism for bioavailability. *Am J Clin Nutr* 2002;76:447-53.
- King RA. Digestion, absorption, and metabolism of isoflavones. In: Gilani GS, Anderson JB, eds. *Phytoestrogens and Health*. Champaign: AOCS Press, 2002:209-34.
- Huggett AC, Pridmore S, Malnoë A, Haschke F, Offord EA. Phyto-oestrogens in soy-based infant formula. *Lancet* 1997;350:815-6.
- Irvine CH, Shand N, Fitzpatrick MG, Alexander SL. Daily intake and urinary excretion of genistein and daidzein by infants fed soy- or dairy-based infant formulas. *Am J Clin Nutr* 1998;68(6 Suppl):1462S-5S.
- Chen A, Rogan WJ. Isoflavones in soy infant formula: A review of evidence for endocrine and other activity in infants. *Annu Rev Nutr* 2004;24:33-54.
- Jabbar MA, Larrea J, Shaw RA. Abnormal thyroid function tests in infants with congenital hypothyroidism: The influence of soy-based formula. *J Am Coll Nutr* 1997;16:280-2.
- Chang HC, Doerge DR. Dietary genistein inactivates rat thyroid peroxidase in vivo without an apparent hypothyroid effect. *Toxicol Appl Pharmacol* 2000;168:244-52.
- Flynn KM, Ferguson SA, Delclos KB, Newbold RR. Multigenerational exposure to dietary genistein has no severe effects on nursing behavior in rats. *Neurotoxicology* 2000;21:997-1001.
- Flynn KM, Ferguson SA, Delclos KB, Newbold RR. Effects of genistein exposure on sexually dimorphic behaviors in rats. *Toxicol Sci* 2000;55:311-9.
- Lewis RW, Brooks N, Milburn GM, et al. The effects of the phytoestrogen genistein on the postnatal development of the rat. *Toxicol Sci* 2003;71:74-83.
- Ojeda SR, Andrews WW, Advis JP, White SS. Recent advances in the endocrinology of puberty. *Endocr Rev* 1980;1:228-57.
- Bennetts HE, Underwood EJ, Shier FL. A specific breeding problem of sheep on subterranean clover pastures in Western Australia. *Aust Vet J* 1946;22:2-12.
- Carter MW, Matrone G, Smart WW Jr. Effect of genistein on reproduction of the mouse. *J Nutr* 1954;55:639-45.
- East J. The effect of genistein on the fertility of mice. *J Endocrinol* 1955;13:94-100.
- Setchell KD, Gosselin SJ, Welsh MB, et al. Dietary estrogens – a probable cause of infertility and liver disease in captive cheetahs. *Gastroenterology* 1987;93:225-33.
- Delclos KB, Bucci TJ, Lomax LG, et al. Effects of dietary genistein exposure during development on male and female CD (Sprague-Dawley) rats. *Reprod Toxicol* 2001;15:647-63.
- Sharpe RM, Martin B, Morris K, et al. Infant feeding with soy formula milk: Effects on the testis and on blood testosterone levels in marmoset monkeys during the period of neonatal testicular activity. *Hum Reprod* 2002;17:1692-703.
- Tan KA, Walker M, Morris K, Greig I, Mason JI, Sharpe RM. Infant feeding with soy formula milk: Effects on puberty progression, reproductive function and testicular cell numbers in marmoset monkeys in adulthood. *Hum Reprod* 2006;21:896-904.
- Faber KA, Hughes CL Jr. The effect of neonatal exposure to diethylstilbestrol, genistein, and zearalenone on pituitary responsiveness and sexually dimorphic nucleus volume in the castrated adult rat. *Biol Reprod* 1991;45:649-53.
- Yellayi S, Naaz A, Szwedzkiowski MA, et al. The phytoestrogen genistein induces thymic and immune changes: A human health concern? *Proc Natl Acad Sci U S A* 2002;99:7616-21.
- Newbold RR, Banks EP, Bullock B, Jefferson WN. Uterine adenocarcinoma in mice treated neonatally with genistein. *Cancer Res* 2001;61:4325-8.
- Strom BL, Schinnar R, Ziegler EE, et al. Exposure to soy-based formula in infancy and endocrinological and reproductive outcomes in young adulthood. *JAMA* 2001;286:807-14.
- Goldman LR, Newbold R, Swan SH. Exposure to soy-based formula in infancy. *JAMA* 2001;286:2402-3.
- Sellers WA, Halpern SR, Johnson RB, Anderson DW Jr, Saperstein S, Shannon BS Jr. New growth charts: Soy, cow, and breast milk comparison. *Ann Allergy* 1971;29:126-34.
- Dean ME. A study of normal infants fed a soya protein isolate formula. *Med J Aust* 1973;1:1289-93.
- Köhler L, Meeuwisse G, Mortensson W. Food intake and growth of infants between six and twenty-six weeks of age on breast milk, cow's milk formula, or soy formula. *Acta Paediatr Scand* 1984;73:40-8.
- Churella HR, Borschel MW, Thomas MR, Breen M, Jacobs J. Growth and protein status of term infants fed soy protein formulas differing in protein content. *J Am Coll Nutr* 1994;13:262-7.
- Lasekan JB, Ostrom KM, Jacobs JR, et al. Growth of newborn, term infants fed soy formulas for 1 year. *Clin Pediatr (Phila)* 1999;38:563-71.
- Mendez MA, Anthony MS, Arab L. Soy-based formulae and infant growth and development: A review. *J Nutr* 2002;132:2127-30.
- ESPGHAN Committee on Nutrition. Soy protein infant formulae and follow-on formulae: A commentary by the ESPGHAN Committee on Nutrition. *J Pediatr Gastroenterol Nutr* 2006;42:352-61.
- Merritt RJ, Jenks BH. Safety of soy-based infant formulas containing isoflavones: The clinical evidence. *J Nutr* 2004;134:1220S-4S.
- Høst A, Halken S. A prospective study of cow milk allergy in Danish infants during the first 3 years of life. Clinical course in relation to clinical and immunological type of hypersensitivity reaction. *Allergy* 1990;45:587-96.
- Bock SA. Prospective appraisal of complaints of adverse reactions to foods in children during the first 3 years of life. *Pediatrics* 1987;79:683-8.
- Schrander JJ, van den Bogart JP, Forget PP, Schrander-Stumpel CT, Kuijten RH, Kester AD. Cow's milk protein intolerance in infants

- under 1 year of age: A prospective epidemiological study. *Eur J Pediatr* 1993;152:640-4.
43. Jakobsson I, Lindberg T. A prospective study of cow's milk protein intolerance in Swedish infants. *Acta Paediatr Scand* 1979;68:853-9.
 44. Klemola T, Vanto T, Juntunen-Backman K, Kalimo K, Korpela R, Varjonen E. Allergy to soy formula and to extensively hydrolyzed whey formula in infants with cow's milk allergy: A prospective, randomized study with a follow-up to the age of 2 years. *J Pediatr* 2002;140:219-24.
 45. Berger-Achituv S, Shohat T, Romano-Zelekha O, et al. Widespread use of soy-based formula without clinical indications. *J Pediatr Gastroenterol Nutr* 2005;41:660-6.
 46. American Academy of Pediatrics, Committee on Nutrition. Hypoallergenic infant formulas. *Pediatrics* 2000;106(2 Pt 1):346-9.
 47. Zeiger RS, Sampson HA, Bock SA, et al. Soy allergy in infants and children with IgE-associated cow's milk allergy. *J Pediatr* 1999;134:614-22.
 48. Bock SA, Atkins FM. Patterns of food hypersensitivity during sixteen years of double-blind, placebo-controlled food challenges. *J Pediatr* 1990;117:561-7.
 49. Bhatia J, Greer F; American Academy of Pediatrics, Committee on Nutrition. Use of soy protein-based formulas in infant feeding. *Pediatrics* 2008;121:1062-8.
 50. The Australian College of Paediatrics. Soy protein formula. *J Paediatr Child Health* 1998;34:318-9.
 51. Tuohy PG. Soy infant formula and phytoestrogens. *J Paediatr Child Health* 2003;39:401-5.
 52. Businco L, Bruno G, Giampietro PG. Soy protein for the prevention and treatment of children with cow-milk allergy. *Am J Clin Nutr* 1998;68(6 Suppl):1447S-52S.
 53. Sampson HA. Utility of food-specific IgE concentrations in predicting symptomatic food allergy. *J Allergy Clin Immunol* 2001;107:891-6.

NUTRITION AND GASTROENTEROLOGY COMMITTEE

Members: *Drs Margaret Boland, Children's Hospital of Eastern Ontario, Ottawa, Ontario; Jeff Critch, Janeway Child Health Centre, St John's, Newfoundland; Jae Hong Kim, UCSD Medical Center, San Diego, California, USA; Valérie Marchand, Sainte-Justine UHC, Montreal, Quebec (chair); Theodore Prince, Calgary, Alberta (board representative); Marli Ann Robertson, Alberta Children's Hospital, Calgary, Alberta*

Liaisons: *Dr George Davidson, BC Children's Hospital, Vancouver, British Columbia (Human Milk Banking Association); Ms Joanne Gilmore, Toronto Public Health, Toronto, Ontario (Breastfeeding Committee for Canada); Dr Frank Greer, Madison, Wisconsin, USA (American Academy of Pediatrics, Committee on Nutrition); Ms Hélène Lowell, Ottawa, Ontario (Office of Nutrition Policy and Promotion, Health Canada); Ms Eunice Misskey, Regina, Saskatchewan (Dietitians of Canada); Ms Rosemary Sloan, Ottawa, Ontario (Public Health Agency of Canada, Health Canada); Ms Christina Zehaluk, Ottawa, Ontario (Bureau of Nutritional Sciences, Health Canada)*

Principal authors: *Drs Alexander Leung, Alberta Children's Hospital, Calgary, Alberta; Anthony Otley, IWK Health Centre, Halifax, Nova Scotia*

The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed.

Variations, taking into account individual circumstances, may be appropriate.

All Canadian Paediatric Society position statements/notes are reviewed, revised or retired as needed on a regular basis.

For the current version, please consult the "Position Statements" section of the CPS website (www.cps.ca/english/publications/statementsindex.htm).