**EDITORIAL**

# Government Distribution of Infant Formula in Chile

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The government of Chile plans to begin distributing starter formula for its infants, raising many questions. The issues are explored here after the following brief description of the context.

**The PNAC program**

The widespread distribution of free milk products for children by national governments can be traced back at least to France's initiative in 1900. Since then, the practice has been adopted by many countries (Memoria Chilena 2016). Chile's program, *Gota de Leche* (A Drop of Milk) was launched in San Bernardo in 1911 and quickly spread to many other parts of the country.

The *Programa Nacional de Alimentación Complementaria* (PNAC) was established in 1987. Its title is commonly translated as the National Complementary Food Program, but it is better described as a supplementary food program because it is intended to supplement diets that might be deficient. In other contexts, complementary foods are those provided to infants to complement breastfeeding beginning around six months of age.

The program addresses the nutritional needs of children under six years of age and their mothers. The service is divided into four categories:

- **PNAC Básico**, for healthy mothers and infants. Purita Fortificada, a powdered milk product, can be obtained for infants through 18 months of age.
- **PNAC Refuerzo**, for infants who are malnourished or at risk of malnutrition.
- **PNAC Prematuros**, for infants who are born prematurely. They are given formula specially designed for premature or low-birth-weight infants.
- **PNAC de Enfermedades Especiales** for children with special diseases. In this category some benefits may be continued until the child reaches 18 years of age.

PNAC Básico serves the largest number of infants. It provides a variety of cow's milk-based food products for both children and their mothers under various rules. Both the composition of the foods provided and the rules have varied over time, based principally on the emergence of new understandings about nutritional needs.

Infants are entitled to Leche Purita Fortificada, a powdered milk product containing 26 percent fat, and fortified with vitamin C, iron, zinc, and copper. The fortified product replaced the plain cow's milk with no additives that PNAC had distributed before 1998 (Rama de Nutrición 1999). It comes in a one-kilogram package. The Ministry of Health occasionally describes it as a type of formula because they add ingredients to the cow's milk, but it is not designed to meet widely accepted international standards for infant formula (Codex Alimentarius Commission 2007).

PNAC advises mothers who provide Purita Fortificada to infants under one-year-old to dilute it

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**Submitted:** 8/20/2016
**Accepted:** 8/22/2016
**Conflict of interest:** None
**Peer-reviewed:** No

and add vegetable oil and sugar, or preferably, maltodextrin. These additives are not provided by PNAC, but must be purchased by the mothers in local stores.

The amounts of Purita Fortificada to which families are entitled are based on their feeding patterns. Women who **exclusively breastfeed** (Lactancia Materna Exclusiva) during the first six months get none during those six months or afterward. Internationally, exclusive breastfeeding is understood to mean no water or formula of any kind, but for the purposes of this program "exclusive" is taken to mean at least 90 percent of the daily feeds consist of breastfeeding.

Women who **predominantly breastfeed** (Lactancia Materna Predominante) get one kilogram a month during the first two months, and then two kilograms a month up to and including the fifth month, and none after that. Women who predominantly breastfeed are those who breastfeed between 50 and 90 percent of the time.

Women who feed **formula predominantly** get two kilograms during each of the first two months, and three kilograms during the third through fifth months, and no formula after that. They also get three kilograms of a cream soup mixture during the fifth month.

Those who feed **formula exclusively** get two kilograms during each of the first two months and three kilograms during the third through eleventh months. They get two kilograms from the twelfth through the seventy first months—up to the child's fifth birthday. They also get one kilogram of a cream soup mixture during the fifth month and two kilograms of the cream soup from the sixth through the seventy-first months (Ministerio de Salud 2011, 10-11).

These arrangements are changing because of a new initiative to replace at least some of the Purita Fortificada with starter formula, *fórmula de inicio* (Ministerio de Salud 2016a, 2016b, 2016c 2016d). The planning document reviews current knowledge of the importance of breastfeeding for both the infant and the mother's health and calls for vigorous support when there are difficulties in breastfeeding. At this writing in mid-2016, pilot studies on the distribution of a starter formula are underway. Starter formula is designed for only the first few months of the infant's life. It is not yet clear what would replace Purita Fortificada as the children get older and starter formula is no longer suitable.

The plan identifies a number of conditions of the mother or child that would make them eligible for free formula from PNAC. If those conditions are not met, there is a possibility of receiving the formula, but only if the mother signs an informed consent form and attends a counseling session on breastfeeding.

**Critical analysis of the plan**

The *Proyecto de Incorporación de Fórmula de Inicio en el Programa Nacional de Alimentación Complementaria (PNAC)* [*] (Ministerio de Salud 2016a) recognizes that, in terms of its impact on infants' health, Purita Fortificada is inferior to the starter formulas offered by major manufacturers. However, both tend to displace breastfeeding. Our central concern is that the new starter formula distribution program might expand to a much larger scale, with more infants consuming it, and with each infant consuming more formula. If it does go to a larger scale, there will be much less breastfeeding. This issue deserves close attention because of the impact it could have on the health of Chile's children and the adults they will become.

Chile's plan for distributing starter formula says that if support for breastfeeding fails, the second best alternative is feeding with formula. That is not correct. In some cases, when conventional direct breastfeeding cannot be done, the mother may be able to express her milk into bottles or pouches.

If the biological mother is unable to produce enough milk, it is possible to obtain human milk from other women through milk sharing arrangements or human milk banks. These alternatives can be developed more fully. If they are well regulated, the human milk they provide would be better for infants' health than any manufactured formula.

The plan says that formulas made from cow's milk have been improved in such a way as to approach the quality of breastmilk (Ministerio de Salud, 2016a, 3). If this taken to mean the quality of formula is *close* to that of breastmilk, it is not true. In practically all studies, the health outcomes for infants fed with formula are worse than those for infants who are breastfed. Manufacturers claims for the quality of new infant formulas are always about comparing a new formula with an older one, and

[*] Project to incorporate starter formula into the PNAC program

saying that the new one is "closer" to breastmilk. Closer is not the same as close. The source cited to support their point (Ministerio de Salud 2014) does not claim that formula is close to the quality of breastmilk.

Many studies have shown that infant formula regularly results in worse health outcomes for infants when compared with breastfeeding (e.g., Bartick and Reinhold 2010; Chen and Rogan 2004; The Lancet 2016). Much of the criticism of infant formula has centered on concerns about its safety, especially in low-income settings, but increasingly it is being recognized that formula is nutritionally inadequate. It produces worse health outcomes even in the best settings (Kent 2012, 2014b).

There is often concern about infant weight gain being either too slow or too fast. The idea that these issues should be addressed through the use of either ordinary or special infant formulas is questionable (Morrison 2015; Thulier 2016). Often weight problems can be managed by improving breastfeeding practices.

In discussing the addition of fatty acids to infant formula, the plan says their benefits have been well demonstrated (Ministerio de Salud, 2016a, 7). That is not correct (Kent 2014a). Indeed, many claims about the benefits of additives in infant formulas are highly questionable (Belamarich, Bochner, and Racine 2016).

The pilot studies involve both changes in the product that is supplied (Purita Fortificada versus starter formula) and in the rules under which they are supplied. It will be difficult to distinguish which changes in impacts are due to changes in the product and which are due to changes in the rules. It would be wise to conduct some studies in which only the rules are changed. Rules that limit the availability of free food for infants would be likely to increase the breastfeeding rate, and thus improve infants' health, regardless of which food is offered.

Table 1 of the planning document (Ministerio de Salud 2016a) lists conditions under which women can receive starter formula from PNAC for their infants. They include diagnoses such as HIV/AIDS or herpes, and mothers who use drugs incompatible with breastfeeding or who are undergoing certain types of chemotherapy. This list of conditions was based on the World Health Organization's list of medical reasons for using breast-milk substitutes (World Health Organization 2009).

Much of that information is now outdated. For example, instead of being advised to use formula, women with herpes lesions on their nipples could be supported in expressing their breastmilk and feeding it to the infant with a tube or bottle. Similarly, women who are diagnosed as HIV-positive are no longer advised to avoid breastfeeding because of fear of transmitting the virus to their infants through the breastmilk. Antiretroviral drugs can be taken by breastfeeding women to essentially eliminate the risk of HIV transmission while preserving the health advantages of breastfeeding (National Institutes of Health 2016; World Health Organization and UNICEF 2016). For a time, the United Nations Children's fund distributed infant formula to prevent HIV transmission through breastfeeding, but they have discontinued this practice (de Wagt and Clark 2004).

The WHO document on medical reasons to use breastmilk substitutes did not anticipate the rapid advances in the establishment of human milk banks in recent years. Worldwide, many critically ill infants in neonatal intensive care units who are too weak to suckle are provided with their own mother's milk indirectly, or other women's milk, through human milk banks.

There have been advances in methods of delivery of human milk to infants. Some women who are unable to breastfeed directly in the conventional way can express their milk and deliver it through a tube or bottle (The Mighty Staff 2015). Or they could deliver milk obtained from another woman. The human milk can be fed to the infant by the mother, the father, or another caretaker. In many cases, direct skin-to-skin contact can be arranged.

It is unfortunate that Chile has only one human milk bank for the entire country (Viñals 2015). Brazil has more than 200 (Fox News Latino 2014). If Chile had a fully developed network of milk banks, there would be much less need for infant formula.

Chile's plan anticipates providing formula if mothers or infants have some of the specific medical conditions identified in the WHO document (World Health Organization 2009). In addition, some mothers would be able to obtain formula if they sign informed consent statements. The statement would document that the woman is aware of the benefits of breastfeeding and, having attended a counseling session about it, she nevertheless wants to forego breastfeeding (Ministerio de Salud 2016d, 5). It is

not clear whether there would be any limits to the number of families that could use this consent procedure and get free formula on request. Chile might follow the pattern in the United States, where most low-income mothers qualify for the WIC program and therefore can get free formula for their infants. The result is that WIC provides formula for about half the infants in the country (Kent 2006, 2011).

Chile's plan makes a brief reference to the human right to adequate food, and points out that under that body of law the state cannot deny children's right to adequate food (Ministerio de Salud 2016d, 5). This is correct, but it does not mean the state is obligated to provide that food (Kent 2005).

The World Health Organization document of 2009 was about medical reasons for using breast-milk substitutes. It was not about the conditions under which free formula should be supplied by the government.

The government's plan for providing starter formula should be based on a thorough analysis of not just of the likely health impacts, but also of the economic impacts for the government and for the families.

Purchasing the formula would be very costly for the government, as seen already in the pilot program. The costs for staff and offices to operate the program also would be substantial, especially where there are complex criteria and rules for deciding who is to get what.

The program would be costly to families for several reasons. The free formula would be provided only for a limited time, after which the families would have to pay for formula themselves. Mothers who breastfeed for the first six months would be able to continue breastfeeding, along with providing other foods, after that first six months, but women who stopped lactating would have to purchase formula after PNAC stopped supplying it for free.

In Chile, less educated mothers are more likely to breastfeed (Ministerio de Salud 2013). Making free formula available to them – a highly valued product, with the apparent endorsement of the government – would attract them to the formula and reduce their breastfeeding rates. It could also lead to greater dependence on commercial processed foods over the long term, thus increasing these families' economic burdens.

The cost of formula purchased by the government could be reduced by using generic formula rather than well-known brands. However, the producers of generic formula would be less likely to bid to supply the product. They would be reluctant because they would not be able to reap the benefits of winning brand loyalty. That brand loyalty would be based on the apparent endorsement by the government of whatever brand wins the contract.

Studies of the WIC program in the United States show that the retail market prices of well-known brands of formula are likely to increase as a result of their winning the contract to supply the formula distributed by the government. This means there would be increasing costs for all buyers of that formula, whether or not they had received free formula from the government in the past. The distribution of free formula by the government would provide substantial benefits for the manufacturers, going well beyond the short-term profits from their contracts with the government.

**Ethical dilemmas**

Chile's Ministry of Health is concerned about an ethical dilemma. People with low incomes have been able to get Purita Fortificada from the government for free while people who have money can purchase higher quality commercial infant formula in the marketplace (Stipicic 2016). This is indeed a serious matter. However, there are other concerns as well.

While starter formula might be better for infants' health than Purita Fortificada, the most important difference might be that mothers perceive starter formula as a more valuable commodity. This could result in an increased incentive to seek formula from PNAC and a reduced incentive to breastfeed.

That this sort of response is likely is evident from the United States' experience. The Special Supplemental Nutrition Program for Women, Infants, and Children (commonly known as WIC*)* distributes free infant formula and also supports breastfeeding. Thus its objectives are similar to those described in Chile's program. The planners of Chile's project recognize that the provision of infant formula in the WIC program interferes with breastfeeding (Castillo and Power 2016; Kent 2006, 2011; Ministerio de Salud 2016a, 7; Ryan and Zhou 2006; Ziol-Guest and Hernandez 2010). What is

there in Chile's plan that would prevent that interference?

In the WIC program the formula distribution effort is far larger than the breastfeeding support effort. Perhaps Chile's plan is to somehow increase the prevalence of breastfeeding despite the introduction of starter formula, by putting more resources into that work. If that is their intention, it should be stated explicitly, and the means for achieving that outcome should be described.

The pivotal question is whether the provision of free formula in Chile's program will be tightly controlled and limited to cases of compelling need.

In the United States the economic and political influence of the formula manufacturers has tipped the balance in favor of expanded formula distribution. Formula sales are also expanding across the globe. The economic interests of the formula industry are driving a steady deterioration of breastfeeding practices throughout the world (Baker et al. 2016; Kent 2015; Smith, Salmon, and Baker 2016).

Many of the conditions under which the planners in Chile believe starter formula would be necessary could be addressed in other ways. Support for breastfeeding could be strengthened without introducing a new formula product. Well-funded lactation clinics could be established in every primary health center. Some of the money that governments would devote to buying infant formula could instead be used to start well-managed human milk banks, or to provide general food subsidies for people with very low incomes. Human milk sharing programs could be developed. Many things could be done without introducing a new type of formula.

The supply of free food by the government in Chile began at a time when the country was poor and malnutrition was a serious problem. Now that conditions have greatly improved the rationale for this support for the general population is weak. It still makes sense to supplement the diets of people who are very poor or have special needs, but in modern times that should be done only for a small portion of the population. If free food is provided, it should not be an expensive highly processed food with questionable impacts on health. There is no equity argument that justifies the distribution of free infant formula.

What is the problem that would be solved by distributing free infant formula? Clearly, there is a need for serious discussion about the wisdom of governments providing free infant formula.

The implementation proposal for the project calls first for defining a target group for the new product, and second it calls for strengthening actions to protect breastfeeding in that target group (Ministerio de Salud 2016a, 3). The title of the document says the project is about introducing starter formula into the PNAC program. Apparently the primary purpose of the project is the introduction of starter formula: promoting breastfeeding is a secondary goal.

The Ministry of Health says it intends to work toward increasing the prevalence of breastfeeding. If that is the most important objective, the priorities should be reversed. The entire project would be more attractive if the first priority was to increase breastfeeding rates, and the government committed to the idea that the number of infants getting either Purita Fortificada or starter formula would be steadily reduced each year in the future. Families would still be free to purchase these products in the same way they purchase other foods. This phase-out would only mean that the government would not provide the products for them.

The World Health Organization and many other agencies recommend that infants should be exclusively breastfed for the first six months. The provision of any sort of food for infants by government during the first six months should be phased out. That goal and a specific plan for phasing out provision of free formula should be set out in a revised plan.

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