



Nutricia North America Marketing of Breastmilk Substitutes Disclosure

Introduction to Nutricia North America

Nutricia North America is a subsidiary of Danone S.A., a global food and beverage company with the mission of bringing health through food to as many people as possible. Nutricia North America sells products for use by infants with special medical conditions under the following brands: Anamix Early Years, Fortini Infant, Neocate Infant, Neocate Syneo Infant, Pepticate Infant, Pepticate Syneo Infant and Periflex Early Years. Those products are designated by Danone as infant Food for Special Medical Purposes (FSMP) (in the US, FSMPs are termed “medical foods”) that are prescribed by healthcare practitioners, that may qualify as Breast Milk Substitutes (BMS) according to the World Health Organization (WHO). Nutricia North America has operations and sales in the United States and Canada, where the infant FSMP represented 31% of 2022 revenues. In that context, infant FSMP represents less than one-third of the Nutricia North America revenues.

Company Comments:

Danone global Policy for the Marketing of Breastmilk Substitutes (“Danone’s policy”) defines breastmilk substitutes (Covered Products) in a different/narrower way than the broad definition mentioned in the WHO implementation manual 2017¹. See Definition/Scope of Products Included in WHO Code and Danone’s Policy in pages [2 to 4] of this memo.

1. B Lab Standards Advisory Council criteria for companies involved in the Marketing of Breastmilk Substitutes and Complementary Foods

As a subsidiary of Danone S.A, Nutricia North America must abide by [Danone's Policy](#). As determined by B Lab’s independent Standards Advisory Council, companies involved in the marketing of breastmilk substitutes are eligible for B Corp Certification if they meet specific requirements for the industry, including disclosure of their practices. These requirements vary by type of company, including whether the company’s practices related to the marketing of breastmilk substitutes is assessed in the Access to Nutrition Index.

Subsidiaries of ATNI listed companies are eligible to certify if:

- The parent company meets the eligibility requirements established based on performance of the Access to Nutrition Index (a minimum score of 55% to be eligible for certification, and 75% by 2030), the subsidiary has applied the parent company’s policy and adheres to national law when those laws are more stringent than the parent company’s policy, or

¹ [Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children](#) (2017).



- The parent company does not meet the eligibility requirements above, but the subsidiary meets the immediate expectations of the BMS Call to Action at the time of certification and achieves full Code compliance by 2030.

All manufacturers of BMS/CF are required to support legislation fully aligned with the Code as well as disclose their policies on lobbying, specific lobbying practices as they relate to BMS/CF, and areas of non-compliance with the Responsible Lobbying Framework (RLF) disclose how the company manages compliance to the Code, and be transparent about potential areas of non-alignment.

As a subsidiary of Danone S.A., Nutricia North America is eligible to be assessed against the above B Lab Standards Advisory Council criteria for companies involved in the marketing of Breastmilk Substitutes and Complementary Foods. For more information on B Lab's position on the marketing of breastmilk substitutes, please refer to B Lab's statement on the breast milk substitute industry and B Corp Certification [here](#).

Nutricia North America and B Corp Certification Eligibility

Danone S.A.'s alignment with the WHO Code and subsequent WHA Resolutions has been externally assessed by the [Access to Nutrition Index, receiving an overall score of 68%, ranking number one in the ATNI – BMS/CF Index 2021](#). Nutricia North America applies Danone S.A.'s policy and adheres to all national laws when those laws are more stringent than its policy. Therefore, Nutricia North America is eligible for B Corp Certification.

While Nutricia North America has not been separately assessed by the Access to Nutrition Index, Danone's global policies on the marketing of breastmilk substitutes applies to Nutricia North America.

2. Areas of Non-Alignment with the WHO Code

In addition to the commitment to the WHO Code, a number of Danone's policies align entirely with the provisions of the WHO Code. Nutricia North America has identified and acknowledges the following areas where Danone's policies may not align with the WHO Code, or where there may be differing interpretations in how the WHO Code and WHA Resolutions should apply:

Definition/Scope of Products Included in WHO Code and Danone's Policy

Danone's policy regarding the marketing of breastmilk substitutes applies to a scope of products that differ from the complete scope of the WHO Code.

Article 2 of the WHO Code states "The Code applies to the marketing, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle fed complementary foods, when marketed or

otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.” Breastmilk substitutes are defined as “Any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose.”

Danone Policy applies to “Covered Products,” which include “Infant Formula (formulated to meet the normal nutritional requirements of infants up to the age of six months) and information concerning its use, any other food or beverage that is presented to be a partial or total replacement for breastmilk, for infants up to six months of age, whether or not suitable for that purpose, and information concerning their use [and], delivery products (such as bottles and teats) and information concerning their use.”

In Danone’s policy, “Excluded Products are all products, other than Covered Products, produced or sold by Danone, including modified milks for children and products intended for use by infants with special medical conditions.

In addition, as per ATNI assessment, in Danone’s policy, products that are not defined as Covered Products, but that are produced or sold by Danone, include:

- (1) Follow on formula in low risk countries.
- (2) Growing up milks for 12 - 36 months,
- (3) Complementary food and drinks for infants, when labelled for 6 - 36 months or such a lower age as may be mandatorily required by local legislation, provided they do not contain instructions for modification for use as a BMS,
- (4) FSMPs or their equivalent in a country, that are designed for infants with medical conditions who are unable to absorb, digest or metabolise breast milk or standard infant formula as a sole source of nutrition, are under medical supervision and are at risk of death or compromised growth and developmental potential without access to these products, and
- (5) Milk products not adapted for infant feeding.

The products commercialised by Nutricia North America fall under the category of the Foods for Specific Medical Purpose (FSMPs), which are not included in the scope of the Danone policy. Nutricia North America does not sell any products that fall within the scope of Danone’s Policy. The WHO Code does not make a distinction between FSMPs and other formulas.

Food for Special Medical Purposes (FSMP) is not considered as part of the scope of Danone’s policy as breastmilk substitutes due to their use in patients with a diagnosed medical condition who, because of their condition, have specific nutritional needs that cannot be met by a normal diet. These products are prescribed or recommended by a healthcare professional. It is for these reasons that FSMPs are not considered as breast milk substitutes.

The WHA Resolution [69.9](#) defines a breastmilk substitute as any food being marketed or otherwise presented as a partial or total replacement for breastmilk, whether or not suitable for that purpose which includes infant milks marketed as food for special medical purposes (FSMP).

Products for infants with special medical conditions are a unique category. They are used under medical supervision, making sure that the infant and/or child is receiving the appropriate nutritional support to ensure optimal growth and development, either in an acute clinical situation or for chronic conditions. Without the support of these products, infants may have their nutritional status compromised, making them more prone to related complications. In Europe, this category is subject to specific legislation, (EU) No 609/2013.²

Company Comments:

Nutricia North America sells foods for special medical purposes, FSMPs. These products are specially formulated for infants who are unable to tolerate, absorb, digest or metabolize breast milk or standard infant formula or have other medically determined nutrient requirements (e.g. allergy to whole proteins) that cannot be met by breast milk or standard infant formula, and are used under medical supervision for patients at risk of malnutrition, abnormal development or death without access to these products.

As these products are introduced by the Healthcare Professional (HCP) to respond to the specific nutritional needs of the medical condition that cannot be met by breastfeeding alone, they should not be considered the same as a breast milk substitute for a healthy infant.

As these products are prescribed/recommended and their use monitored by an HCP following a diagnosis of a disease, disorder or medical condition, use of FSMPs is beyond the decision of the mother to breastfeed.

Next Steps

As stipulated by the requirements for B Corp Certification, Nutricia North America will remain eligible for B Corp Certification as long as their parent company, Danone remains above the 55% threshold and/or the company remains in the top 20% of companies on the index and works towards the advanced score of 75% by 2030.

Should Danone not maintain any of these requirements, Nutricia North America would not automatically lose the certification, as long as the parent company Danone has a time bound remediation plan and is able to achieve the 75% threshold in the next instance of the ATNI index. In the case where Danone does not achieve that, Nutricia North America would be expected to meet the immediate expectations of the BMS Call to Action and achieve full Code compliance by 2030.

B Lab's Public Complaints Process

² See background at: <https://www.efsa.europa.eu/en/press/news/151126>



Should any party become aware of specific company practices, related or not to this topic, that may constitute:

- Intentional misrepresentation of practices, policies, or claimed outcomes during the [certification process](#), or
- Breach of the core values articulated in our [Declaration of Interdependence](#) within the B Corp Community,

these may be submitted through [B Lab's Public Complaint Process](#).