



Nutricia AMN Greater China Marketing of Breastmilk Substitutes Disclosure

Nutricia AMN Greater China, a Danone company, includes the following entities within the scope of its B Corp certification that must comply with [B Lab's Risk Standards for the Marketing of Breastmilk Substitutes](#):

- Nutricia Trading (Shanghai) Co., Ltd. ("Nutricia SH")
- Nutricia Clinical (Hong Kong) Limited ("Nutricia HK")

In 2022, B Lab Global released its [Risk Standards for the Marketing of Breastmilk Substitutes](#), which initially used the Access to Nutrition Initiative (ATNI) [BMS/ CF Index 2021](#) to evaluate the eligibility of certain companies. B Lab Global recognizes that the ATNI Index has since significantly evolved and is working on updating its standards accordingly. Companies currently on the B Corp certification journey will have to abide by the revised B Lab standards, once available, during their next recertification.

Introduction to Nutricia SH

Nutricia Trading (Shanghai) Co., Ltd. (hereinafter referred to as "Nutricia SH") 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 SH sells 4 products for use by infants with special medical conditions under the following brands: Neocate Periflex, Infatrini, Pepti Junior. Those products are designated by Danone as infant Food for Special Medical Purposes (FSMP) that are prescribed by healthcare practitioners, which may qualify as Breast Milk Substitutes (BMS) according to the World Health Organization (WHO). Nutricia SH has operations and sales in China mainland - *for the purpose of this disclosure, China refers to the Chinese Mainland excluding Hong Kong Special Administrative Region (SAR), Macao SAR, and the Taiwan Region*. China belongs to Zone CNAO, where Specialized Nutrition represented 70% of 2023 revenues. In that context, infant FSMP represents the majority of the Nutricia SH's 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 SH must abide by [Danone's Global Policy for the Marketing of Breastmilk Substitutes](#). As determined by B Lab's independent Standards Advisory

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

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 are assessed in the Access to Nutrition Index.

Therefore, subsidiaries of ATNI-listed companies are eligible to certify if:

- The parent company meets the eligibility requirements established based on the performance of the Access to Nutrition Index 2021 (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
- 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 SH 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 SH 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 SH applies Danone S.A.'s policy and adheres to all national laws when those laws are more stringent than its policy. Therefore, Nutricia SH is eligible for B Corp Certification.

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

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 SH 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 SH fall under the category of Foods for Specific Medical Purposes (FSMPs), which are not included in the scope of the Danone policy. Nutricia SH 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 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 SH 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.

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

Next Steps

As stipulated by the requirements for B Corp Certification, Nutricia SH 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 2021 index and works towards the advanced score of 75% by 2030.

Should Danone not maintain any of these requirements, Nutricia SH 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 SH would be expected to meet the immediate expectations of the BMS Call to Action and achieve full Code compliance by 2030.

Introduction to Nutricia HK

Nutricia Clinical (Hong Kong) Limited (hereinafter referred to as “Nutricia HK”) 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 SH sells 18 products for use by infants with special medical conditions under the following brands: Anamix, Fortini, Neocate, Infatrini, Ketocal, Monogen, and Milupa. Those products are designated by Danone as infant Food for Special Medical Purposes (FSMP) that are prescribed by healthcare practitioners, which may qualify as Breast Milk Substitutes (BMS) according to the World Health Organization (WHO). Nutricia HK has operations and sales in the Hong Kong Special Administrative Region (SAR), Macao SAR, and Taiwan. These three regions belong to China, and hereby belong to Zone CNAO, where Specialized Nutrition represented 70% of 2023 revenues. In that context, infant FSMP represents the majority of Nutricia HK’s 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 2017³. See Definition/Scope of Products Included in WHO Code and Danone’s Policy in pages [7 to 9] of this memo.

2. 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 HK must abide by [Danone’s Global Policy for the Marketing of Breastmilk Substitutes](#). 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

³ [Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children](#) (2017).

practices. These requirements vary by type of company, including whether the company's practices related to the marketing of breastmilk substitutes are assessed in the Access to Nutrition Index.

Therefore, subsidiaries of ATNI-listed companies are eligible to certify if:

- The parent company meets the eligibility requirements established based on the performance of the Access to Nutrition Index 2021 (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
- 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 HK 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 SH 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 HK applies Danone S.A.'s policy and adheres to all national laws when those laws are more stringent than its policy. Therefore, Nutricia HK is eligible for B Corp Certification.

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

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 SH 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:

- (3) Follow on formula in low-risk countries.
- (4) 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 HK fall under the category of Foods for Specific Medical Purposes (FSMPs), which are not included in the scope of the Danone policy. Nutricia SH 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) are not considered 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 609/2013.⁴

Company Comments:

Nutricia HK 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

⁴ See background at: <https://www.efsa.europa.eu/en/press/news/151126>



As stipulated by the requirements for B Corp Certification, Nutricia HK 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 2021 index and works towards the advanced score of 75% by 2030.

Should Danone not maintain any of these requirements, Nutricia HK 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 HK 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

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](#).