



Danone US, LLC Marketing of Breastmilk Substitutes Disclosure

Introduction to Danone US, LLC

Danone US, LLC 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. Danone US, LLC sells early life nutrition products that are considered breastmilk substitutes (BMS) according to the World Health Organization (WHO). These products include Happy Baby and Aptamil of Covered Products with operations and sales in the United States of America. The United States of America belongs to the North America zone where Specialized Nutrition represented 6% of 2022 revenues. In that context, BMS represents less than one-third of the United States of 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 [3 to 5] 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, Danone US, LLC 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
- 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,



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



and areas of non-compliance with the Responsible Lobbying Framework (RLF) disclose how the company manages compliance to the Code, and (3) be transparent about potential areas of non- alignment.

As a subsidiary of Danone S.A., Danone US, LLC 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](#).

Danone US, LLC and B Corp Certification Eligibility

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

While Danone US, LLC has not been separately assessed by the Access to Nutrition Index, Danone's global policies on the marketing of breastmilk substitutes applies to Danone US, LLC. Each subsidiary of Danone S.A. adheres to the following compliance standards:

- The Danone BMS Policy is shared with employees involved in marketing of BMS as part of their onboarding process and a BMS declaration statement is signed by each employee within 3 months of joining Danone US, LLC. Induction training on the Danone BMS Policy is organized for new employees within 3 months of joining.
- Employees responsible for the marketing, distribution, selling, education and/or governance of BMS Marketing must undertake an in-depth training (such as e-learning) on the Danone BMS Policy. Additionally, employees of above-mentioned teams receive refresher trainings on the Danone BMS Policy on a yearly basis.
- Furthermore, the Danone BMS Policy is incorporated into contracts with relevant marketing partners of Danone (such as distributors) and employees of these partners are trained.
- A reference to the Danone BMS Policy is made in a letter communication to their commercial third parties.
- Danone internal audits include control points on the Danone BMS Policy and specific external audits are conducted by independent companies on a yearly basis based on a global roadmap. In addition, a yearly self-assessment is conducted on the implementation of the Danone BMS Policy in the local market.
- BMS-related communication materials follow an approval flow via the Danone communication validation management system.



- Allegations of non-compliance with the Danone BMS Policy are monitored and reported by affiliates of Danone S.A. to the Specialized Nutrition General Counsel team on a quarterly basis for consolidation, corrective and/or disciplinary actions as need be.

Company Comments:

Danone supports the WHO's global public health recommendation calling for exclusive breastfeeding for the first six months of age and continued breastfeeding up to two years and beyond, combined with the safe introduction of appropriate complementary foods.²

Danone is committed to delivering high-quality, safe nutrition³ in all markets we operate in: Formula is amongst the most strictly regulated foodstuffs. All our products are manufactured under very strict hygienic and quality management procedures to help ensure the protection, health and safety of infants and young children.

Danone also supports the overarching nutrition and health ambition of WHO, including the global nutrition targets 2025 and the Sustainable Development Goals guiding the international development agenda until 2030.

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. Danone US, LLC 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,

² [WHA34.22](#) (1981) on "International Code of Marketing of Breast-milk Substitutes"; [WHA35.26](#) (1982) on "International Code of Marketing of Breast-milk Substitutes", [WHA27.43](#) (1974) on "Infant nutrition and breast feeding"; [WHA31.47](#) (1978) on "The role of the health sector in the development of national and international food and nutrition policies and plans, with special reference to combating malnutrition"; [WHA33.32](#) (1980) on "Infant and young child feeding"; [WHA37.30](#) (1984) on "Infant and young child nutrition"

³ [WHA34.23](#) (1981) on "Nutritional value and safety of products specifically intended for infant and young child



feeding”



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.”

For countries defined as High Risk Country in Danone Policy, Covered Products are extended to include: (i) Follow-On Formula (intended for infants from six to twelve months of age) and information concerning its use, (ii) Complementary (weaning) foods and drinks for the use by infants under six months of age, and (iii) Any other any other food or beverage that is presented to be a partial or total replacement for breastmilk for infants and children.

Higher Risk Countries are listed in Appendix 1 to the Danone BMS Policy and are defined as those countries that meet either of the following criteria: (i) More than 10 per 1000 (under 5 years of age) mortality rate; (ii) More than 2% acute malnutrition (moderate and severe wasting) in children under the age of 5 years. The WHO Code does not make a distinction between different countries.

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) iFSMPs or their equivalent in a country (other than the product range mentioned under (ii) above), 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.



Based on Danone Policy from 2016 onwards, Danone does not advertise or promote infant formula for children aged 0-6 months, anywhere in the world, even if permitted by local laws – and was the first company to take such a commitment.

Danone's approach is to implement strict global standards for marketing of BMS around the world, with tighter requirements in countries where there is greater risk to infant health. Under the Danone Policy, several countries are therefore defined as “higher risk” ([following the FTSE4Good criteria](#)) and all other countries are considered as “low risk”.

- United States of America where Danone US, LLC sells breast milk substitutes, is considered as a low-risk country in Danone Policy and therefore the definition of Covered Products in those countries therefore includes Infant Formula (0-6 months) and information concerning its use.

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

WHA Resolutions Subsequent to the WHO Code:

Since the adoption of the WHO Code, a number of World Health Assembly resolutions have either added to, revised, or clarified the content of the original WHO Code. A list of resolutions that may be deemed relevant to individual company practices, but that have not been incorporated into Danone's own policy at this time, including [WHA 39.28](#) (1986), [WHA 45.34](#) (1992), [WHA58.32](#) (2005) and [WHA69.9](#) (2016)

Company Comments:

Danone strongly believes that formulas for young children are not intended to replace breast milk. They can be used in conjunction with continued breastfeeding similarly to other complementary foods. This interpretation does not align with the WHO Guidance issued in 2017 and prepared by a series of WHA resolutions⁵.

Danone is also dedicated to continuous product improvement leading to a better nutritional status of the infants and young children, and we believe that BMS manufacturers have an essential role to play in supporting educational scientific advancement for mothers and young children nutrition. This includes educational events to inform the healthcare system and discuss scientific and factual information about our products and services.

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

⁵ [WHA69.9](#) (2016) and the [Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children](#)



(2017).



In some cases, and following unsolicited requests, we support healthcare organizations with free/subsidized supplies⁶. This is not aligned with the strict interpretation of WHA 39.28 (1986) and WHA 45.34 (1992).

Finally, Danone strives for meaningful and educational information on product labels. We do not apply the labelling provisions outlined in WHA resolution WHA58.32 (2005)⁷ which requires a statement that infant formula may contain pathogenic microorganisms as we believe this may result in scaring mothers.

3. Management Practices of the Company

In accordance with Danone's Policy on the marketing of breastmilk substitutes, Danone US, LLC has the following management practices in place to manage compliance:

Danone ensures that a third party (Bureau Veritas) is engaged to undertake an external verification of compliance with the Danone Policy in no less than three business units every year. Danone publishes the summary reports of such external verifications every year on [Danone.com](https://www.danone.com). Yearly a report of all substantiated allegations of non-compliance with the Danone Policy is compiled by Danone and published on [Danone.com](https://www.danone.com), which summarizes the allegations made and the actions taken for each substantiated allegation.

In addition, as part of the established internal audit protocol of Danone, internal verifications are conducted on business units operating within the scope of the Danone Policy. Each business unit is also responsible for an annual self-assessment of its compliance with the Danone Policy and adequate remediation plan to address improvement areas.

On a yearly basis, an internal summary report is prepared on all matters related to management and compliance with the Danone Policy and is presented to the Specialized Nutrition division and executive vice president and, ultimately, to Danone S.A.

4. Lobbying

Danone discloses its approach to lobbying and advocacy in its global [Advocacy Policy](#). Within the policy, they address the topic of breastmilk substitutes by stating:

"We are committed to fostering a proactive, constructive and evidence-based dialogue supporting breastfeeding around the world and endorse the principles of openness, transparency and integrity in our advocacy activities. Danone is indeed committed to supporting the design and implementation of advocacy initiatives in every country where

⁶ Through a transparent established procurement process upon unsolicited requests, which sometimes include requests for provision of low cost supplies, for babies who must be fed with infant formula during their stay at healthcare organizations, following medical advice

⁷ [WHA58.32 \(2005\)](#) on "Infant and young child nutrition"



it operates that will contribute to creating the right environment for universal WHO Code compliance.”

Danone engaged with Carnstone, an independent management consultancy that developed the [Responsible Lobbying Framework, and their policies and practices were assessed independently against the framework](#) by ATNI in May 2021, based on the 2017 version of the Danone Advocacy Policy (NB: Danone had successively updated its Advocacy in December 2019, then in July 2020). Final outcomes of the report showed that Danone reached a score of 58%, ranking in second position of the breast milk substitutes manufacturers. Danone scored zero points in several areas within the framework on topics concerning Crowding out, Political donations, Alignment of lobbying principles and practices, Narrative on lobbying practices, Examples of implementing commitments in respect of lobbying in the public interest, Examples of implementing commitments on the approach to lobbying, Auditing, and External stakeholder involvement.

Company Comments:

Although Danone is permitted to engage in lobbying activity, including on policies related to infant formula, our company does not lobby on policies that disparage the use of breastmilk, or on policies that promote the use of BMS over breastmilk. Rather, and as recalled in Danone's answer to the BMS Call to Action, we offer to work together with the UN, WHO, governments, civil society organizations, and paediatric societies to develop a new evidence-based, shared policy agenda, focused on increasing breastfeeding rates and improving nutritional health of infants and mothers.

In Danone's 2020 Advocacy Policy, a number of the points made in the 2021 ATNI report were addressed especially with regards to the Legitimacy pillar of the Responsible Lobbying Framework, but also on Political Donations, Auditing and External stakeholder involvement. In particular, Danone disclosed an exhaustive list of its corporate trade association and business partnerships / memberships, alongside the Board seats held.

Danone US, LLC is a member of the Consumer Brands Association (CBA), the International Dairy Foods Association (IDFA), and the Food Marketing Institute (FMI). We are fully committed to transparency and believe that people should have access to publicly available information from all organizations that engage with elected officials.

Next Steps

As stipulated by the requirements for B Corp Certification, Danone US, LLC 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, Danone US, LLC 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, Danone US, LLC 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](#).

