



Introduction:

Mellin Spa is a subsidiary of Danone S.A., a multinational company with the mission of bringing health through food to as many people as possible. Mellin Spa sells 10 infant formulas and a variety of complementary food products under the brands Mellin and Aptamil that qualify as breast milk substitutes (BMS) with operations and sales in Italy.

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 (1) have a formal policy endorsing the [WHO's International Code of Marketing of Breast-milk Substitutes](#), and subsequent World Health Assembly (WHA) resolutions, (2) disclose how the company manages alignment to the code, and (3) are transparent about potential areas that do not align with the code. Companies who are listed in the Access to Nutrition Index are also required to meet minimum score requirements (TBD) on the breast milk substitute scorecard in order to be eligible for B Corp certification.

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](#).

As a subsidiary of Danone S.A., [Danone's global Policy for the Marketing of Breastmilk Substitute \("Danone's Policy"\)](#) is applied to Mellin Spa. Danone's policy includes a commitment to the principles of the WHO Code:

"Danone acknowledges the importance of, and commits to the principles of, the International Code of Marketing of Breast-Milk Substitutes adopted on 21st May 1981 (the "WHO Code") and the subsequent relevant resolutions of the World Health Assembly ("WHA")."

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.¹

Danone is committed to delivering high-quality, safe nutrition² in all markets we operate in: Formula is amongst the most strictly regulated of all foodstuffs. All our products are

¹ [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"

² [WHA34.23](#) (1981) on "Nutritional value and safety of products specifically intended for infant and young child feeding"

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 2030.³

In addition to the commitment to the WHO Code, a number of Danone's policies align entirely with the provisions of the WHO Code. Mellin Spa 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:

Definitions / Scope of Products included in WHO Code and Danone 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 bottlefed 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."

For countries defined as Higher Risk Countries in Danone's 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 [and] (ii) Complementary (weaning) foods and drinks for the use by infants under six months of age.

Higher Risk Countries are listed in Appendix 1 to the Danone 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

³ [WHA65.6](#) (2012): "Comprehensive implementation plan on maternal, infant and young child feeding", [WHA59.21](#) (2006) on "Infant and young child nutrition"

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 products intended for use by infants with special medical conditions. These infants have limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete breast-milk or certain nutrients contained therein or metabolites, or other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet alone. These products are specially formulated to be compositionally distinct from Infant Formula intended for healthy infants."

Company Comments:

Danone's approach is to implement strict global standards for marketing of BMS around the world, with tighter requirement 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".

Italy, where Mellin Spa sells breast milk substitutes, is considered as low risk country in Danone policy and therefore the definition of Covered Products includes Infant Formula (0-6 months) complementary foods (4-6 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 formula for young children are not intended to replace breast milk. They can be used in conjunction with continued breastfeeding similarly to other

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

complementary foods. This interpretation does not align with the WHO Guidance issued in 2016 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 information about our products and services.

Such educational events for the healthcare system run counter to a strict interpretation of the WHO Guidance. It is important to note, however, that the WHA “[welcomed](#)” the WHO Guidance but acknowledged importantly that its implementation should be “in accordance with national context” and “taking into account existing legislation and policy, as well as international obligations”.

In some cases, and following unsolicited requests, we support healthcare organizations with free/subsidized supplies⁶. This is not aligned with 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 labeling 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.

Other Areas of Potential Misalignment:

In addition to the above categories regarding the Scope of Product Definitions and WHA Resolutions, there are other components of Danone’s policy that stakeholders may or may not interpret as aligning (materially or immaterially) with the letter or intent of the WHO Code, including potential variances in language, level of detail, or exceptions.

Examples include:

- Danone’s policy allows inexpensive gifts to health workers on an infrequent basis in acknowledgment of significant national, cultural or religious events, provided such items do not display Covered Products’ (or Danone services’) brand names or logos, whereas the WHO Code simply states “No financial or material inducements to promote products within the scope of this Code should be offered.”

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

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”

- Danone marketing materials include the statement that “The social and financial implications of using infant formula should be considered. Improper use of an infant formula or inappropriate foods or feeding methods may present a health hazard.” WHO Policy states that materials should “include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breast-milk substitutes.”

A detailed breakdown of the WHO Code alongside Danone policy is available as an appendix to this document for interested parties who would like to do their own review of the two. Danone’s alignment with the WHO Code and subsequent WHA Resolutions has also been [externally assessed by the Access to Nutrition Index, receiving an overall score of 46%](#). Mellin Spa itself has not been assessed by the Access to Nutrition Index.

Company Comments: Based on Danone Policy from 2016 onwards, Danone is the first and so far the only company which does not advertise or promote infant formula for children aged 0-6 months, anywhere in the world, even if permitted by local laws.

Management Practices of the Company:

In accordance with Danone’s Policy on the marketing of breastmilk substitutes, Mellin Spa 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](#).

Yearly a report of all substantiated allegations of non-compliance with the Danone Policy is compiled by Danone and published on [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.

Danone has also met the requirements of the FTSE4Good standards related to the marketing of breastmilk substitutes. Two independent audits were conducted by PwC as part of the FTSE4Good process and the findings, are publicly available, including the following areas for improvement:

1. Formalized country manuals
2. Increased awareness of Danoneethicsline.com
3. Correct use of branding towards Health Care Professional's with regards to promotional materials
4. Increased the ability to influence third party retailers in preventing promotions
5. Cross-promotion of different stage formulas where marketing of later stage products may, through similar branding, promote earlier stage products