

## **Nestlé Healthcare Nutrition Marketing of Breastmilk Substitutes Disclosure**

### **Introduction to Nestlé Healthcare Nutrition d/b/a Nestlé Health Science U.S.**

Nestlé Healthcare Nutrition d/b/a Nestlé Health Science U.S. is a nutritional science company based in the United States that offers active lifestyle nutrition, medical nutrition, and pharmaceutical solutions. Under its medical nutrition portfolio, Nestlé Healthcare Nutrition manufactures and sells foods for special medical purposes 0 -12 months and 12 - 36 months that are considered breastmilk substitutes according to the World Health Organization (WHO). These products are sold under the brands Alfamino® Infant, Alfamino® Junior and Alfamino® Junior Vanilla. In 2021, these products account for 0.5% of sales for Nestlé Healthcare Nutrition.

#### *Company Comments:*

Contrary to routine infant formulas that are consumed by healthy babies as a substitute to breast milk, Alfamino® hypoallergenic free amino acid products are designed to address the specific needs of babies with medical conditions and must be used under medical supervision. In Nestlé Policy for implementing the WHO Code, Alfamino® products are considered as Food for Special Medical Purpose. These are products designed for babies 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 specialized products.

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

As a subsidiary of Nestlé S.A, Nestlé's [Global Policy for implementing the WHO Code \("Nestlé's Policy", effective on January 1<sup>st</sup> 2023\)](#) is applicable to Nestlé Healthcare Nutrition. 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, 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 Nestlé S.A, Nestlé Healthcare Nutrition 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](#).

### **Nestlé Health Science US and B Corp Certification Eligibility**

Nestlé 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 57%, ranking number two in the ATNI – BMS/CF Index 2021](#). Nestlé Healthcare Nutrition applies Nestle S.A.'s policy and adheres to all national laws when those laws are more stringent than the policy. Therefore, Nestlé Healthcare Nutrition d/b/a Nestlé Health Science is eligible for B Corp Certification.

The products included in the scope of the Nestlé policy that require practices beyond local legislation are not sold by Nestlé Healthcare Nutrition, but the company abides by relevant national regulations in the United States. To ensure this, Nestlé has the following actions in place:

- A Regulatory Affairs department in the U.S. responsible for ensuring all regulations applicable to their products are implemented and staying up to date with the evolving regulatory requirements in the market. Regulatory Affairs, Medical Affairs and Legal & Compliance review their marketing practices according to scientific accuracy, applicable regulations, and U.S. laws.
- Employees are expected to abide by the [Corporate Business principles](#) and [the Code of Business conduct](#) which includes Compliance as a key principle. Training is organised to ensure they are compliant.
- [Whistleblowing mechanisms](#) are in place to facilitate any stakeholder reporting, anonymously or otherwise, cases of non-compliant practice with the regulation. All cases are investigated and can, when appropriate, lead to dismissal.

*Company Comments:*

Nestlé S.A was assessed as Highly Compliant in the Philippines and Mexico, the two countries selected by ATNI to assess actual company practices in the market.

## **2. Areas of Non-Alignment with the WHO Code**

In addition to the commitment to the WHO Code, Nestlé's policies indicate a commitment to the WHO Code, as evidenced by the Access to Nutrition Index and information available through the BMS Call to Action. Nestlé Healthcare Nutrition has identified and acknowledges the following areas where Nestlé'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 Nestlé's Policy**

Nestlé's Policy for Implementing the WHO Code 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: breastmilk substitutes, including infant formula; other milk products, food 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."

Nestlé's Policy for Implementing the WHO Code effective as of January 1<sup>st</sup>, 2023, defines strict marketing restrictions that globally apply to:

- all Infant Formulas designed to satisfy the nutritional requirements of healthy Infants from birth to 6 months.
- Bottles and teats.

In Higher Risk countries, the provisions of this Policy additionally apply to:

- All Follow-on Formulas designed to satisfy the nutritional requirements of healthy Infants from 6 to 12 months.
- Complementary Foods and drinks for Infants younger than 6 months.

The above products are collectively referred to as Covered Product in Nestlé Policy for Implementing the WHO Code.

The provisions of this Policy do not apply to the below products:

- Complementary Foods and drinks for Infants in Lower Risk countries, and, in Higher Risk countries, when labelled for use after six months of age 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.
- Products which do not fall within the definition of Covered Products (particularly those that are classified as Foods for Special Medical Purposes – FSMPs – or their equivalent in a country, and that are designed for Infants and young children with medical conditions who are unable to absorb, digest or metabolise breast milk or standard formulas as a sole source of nutrition, who are under medical supervision and who are at risk of death or compromised growth and developmental potential without access to these products).

In all countries, Nestlé complies with local regulation implementing the WHO Code to the extent it is stricter than the provisions of this Policy. As a minimum, Nestlé applies all local regulations on other Infant and baby food products.

Nestlé's definition of Higher Risk Countries are based on the [FTSE4Good Inclusion Criteria for the Marketing of Breast Milk Substitutes](#) (listed in Appendix A) and 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 United States, where Nestlé Healthcare Nutrition operates, is not categorised as a higher risk country.

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

- (1) Follow on formula and growing up milks for 12 - 36 months,
- (2) 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,
- (3) 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
- (4) Milk products not adapted for infant feeding.

The products commercialised by Nestlé Healthcare Nutrition such as Alfamino® fall under the category of the Foods for Special Medical Purpose (FSMPs), which are also not included in the

scope of the Nestlé policy. The WHO Code does not make a distinction between different countries or between FSMPs and other formulas.

*Company Comments:*

Nestlé policy for implementing the WHO Code aligns entirely with the provisions of the WHO Code and subsequent relevant WHA resolutions as implemented in the FTSE4Good BMS criteria.

Alfamino® products are classified as Food for Special Medical Purposes. In the US, the same products are classified and notified to the US Food & Drug Administration as exempt infant formula in the case of Alfamino® Infant and classified as medical food in the case of Alfamino® Junior.

As per Nestlé Policy for Implementing the WHO Code, FSMP are defined as products designed for infants and young children with medical conditions:

- who are unable to absorb, digest or metabolise breast milk or standard formulas as a sole source of nutrition,
- who are under medical supervision and who are at risk of death or compromised growth and developmental potential without access to these products.

For these reasons Alfamino® products must be consumed under medical supervision and are not suitable for healthy infants. This is a highly specialized product that explains why it represents 0.5% of sales for Nestlé Healthcare Nutrition and is not commercialized in the same way as routine infant formula consumed by healthy infant as a substitute to breast milk.

**WHA Resolutions Subsequent to the WHO Code:**

Since the adoption of the WHO Code in 1982, a number of World Health Assembly resolutions have either added to, revised, or clarified the content of the original WHO Code.

Nestlé's Policy for implementing the WHO Code implements all FTSE4Good BMS criteria and the following WHO Code and subsequent WHA resolutions: WHA 39.28 (1986), WHA 45.34 (1992), WHA 47.5 (1994) WHA 49.15 (1996), WHA 54.2 (2001), WHA 55.25 (2002).

Nestlé's policy does not reference or state support for the recommendations made in the technical guidance associated with [WHA69.9](#) (2016).

*Company Comments:*

The Nestlé policy does not reference other WHA Resolutions not required by the FTSE4Good BMS criteria such as WHA 69.9, even if they are in whole or in part implemented by the Policy.

As part of resolution WHA 69.9, the World Health Assembly (WHA) “welcomed with appreciation” the technical guidance on ending the inappropriate promotion of foods for infants and young children.

It is important to point out that this is a substantial difference to the WHA Resolutions referred to by FTSE, where certain requirements are set by the terms “urges” or “requests”. It also differs from the term “adopt”, with which the WHA approved the International Code for the marketing of breastmilk substitutes in 1981.

Subsequently, the Legal Counsel of the WHO Office clarified that “*this Guidance was not approved or endorsed, but was welcomed with appreciation [...]: It is WHO Member States that give meaning to the language they use.*”

In other words, the World Health Assembly could not agree to approve the technical guidance note. Nestlé considers the technical guidance note as a proposal to Member States on how to achieve the objective of WHA Resolution 69.9 and therefore Nestlé complies with the Technical Guidance when it has been translated into regulations by Member States.

### **3. Management Practices of the Company**

In accordance with Nestlé’s policy on the marketing of breastmilk substitutes, Nestlé has the following management practices in place to manage compliance to their policy globally:

- Nestlé trains all employees in their infant nutrition business on the importance of supporting and protecting breastfeeding, including the WHO Code. In higher-risk countries, they also provide regular training to help third parties, with whom they have a direct service relationship, to enable compliance with their Policy and Procedures and national legislation implementing the WHO Code.
- Internal monitoring is performed by their staff at country level during routine work activities (e.g., visits to retailers, reviews, etc.) as well as internal audits which are conducted each year in a number of lower and higher-risk countries in which they operate to verify their adherence to their policies, procedures and national legislations implementing the WHO Code.
- Compliance with the Policy and Procedures, as well as all local measures implementing the WHO Code, are verified by a third party regardless of whether a governmental monitoring system is in place. Assurance Statements concerning these verifications are published on their [global corporate website](#). Their practices are externally assessed every 18 months by the audit firm selected by FTSE Russell as part of its [FTSE4Good BMS Verification Process](#).

- Contractual provisions in the form of WHO Code compliance clauses have been created in their formal agreements with third parties involved in BMS marketing or sales activities, and in higher-risk countries where it is permitted under local legislation.
- Allegations of non-compliance with their Policy and Procedures are investigated and corrective actions are taken as required. All employees are aware that the ultimate sanction for non-compliance is dismissal for employees who deliberately violate this Policy or the local legislation implementing the WHO Code, when appropriate and where it is permitted under local legislation.
- Any violations by third parties with whom they have a direct service relationship, require them to take appropriate corrective actions where permitted under local legislation. Where they have no direct service relationship with a third party, their ability to influence their behaviour is limited. However, they will inform them of the violation in writing and ask them to take appropriate corrective action where permitted under local legislation.
- Yearly, a report of all substantiated allegations of non-compliance with the Nestlé Policy is compiled by Nestlé and published on [Nestlé.com](https://www.nestle.com), which summarises the allegations made and the actions taken for each substantiated allegation.

#### **4. Lobbying:**

Nestlé discloses its approach to lobbying and advocacy on their [corporate website](#). Under their advocacy theme of Nutrition and Health, they state that they advocate for:

“Good nutrition in the first 1,000 days and supporting governments and Civil Society Organizations in the implementation of the WHO Code and subsequent relevant resolutions in a law.”

Nestlé has engaged with Carnstone, an independent management consultancy that developed the [Responsible Lobbying Framework](#) (RLF), and their policies and practices have been assessed independently against the framework in 2021. Final outcomes of the report showed that Nestlé reached #3 rank, with a score of 55%, of the breast milk substitutes manufacturers. Nestlé scored zero points in several areas within the framework on topics concerning Crowding Out, Auditing, Public Interest Cases, Alignment of Lobbying Principles and Practices, Examples of implementing commitments in respect of lobbying in the public interest, Examples of implementing commitments on the approach to lobbying, and External stakeholder involvement.

*Company Comments:*



Although Nestlé 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 breast milk. All of Nestlé's lobbying activities are publicly reported through the Federal Lobbying Disclosure <https://lda.senate.gov/system/public/>.

Nestlé has historically been a member of the Infant Nutrition Council of America. 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, Nestlé Healthcare Nutrition will remain eligible for B Corp Certification as long as their parent company, Nestlé 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 Nestlé not maintain any of these requirements, Nestlé Healthcare Nutrition would not automatically lose the certification, as long the parent company Nestlé 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 Nestlé does not achieve that, Nestlé Healthcare Nutrition would be expected to meet the immediate expectations of the BMS Call to Action and achieve full Code compliance by 2030.