

DISCLOSURE MATERIALS

Certified B Corporations must complete a Disclosure Questionnaire to identify potentially sensitive issues related to the company (e.g. historical fines, sanctions, material litigation, or sensitive industry practices).

This component does not affect the company's score on the B Impact Assessment. If the company answers affirmatively to any items in the Disclosure Questionnaire and B Lab deems them to be material, the company must:

- 1) Be transparent about the disclosure issues identified on the company's public B Impact Report
- 2) Describe how the company has addressed this issue.
- 3) Demonstrate that management systems are in place to avoid similar issues from arising in the future.

In all cases, the Standards Advisory council reserves the right to refuse certification if the company is ultimately deemed not to uphold the spirit of the community.

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to background checks by B Lab staff. Background checks include a review of public records, news sources, and search engines for company names, brands, executives/founders, and other relevant topics.

Sensitive issues identified through background checks may or may not be within the scope of questions in the Disclosure Questionnaire, but undergo the same review process and are subject to the same possible review by the Standards Advisory Council, including ineligibility for B Corp Certification, required remediation, or disclosure.

This document contains a copy of the company's completed Disclosure Questionnaire and related disclosure documentation provided by the company.

DISCLOSURE QUESTIONNAIRE

Company Name: Danone Nutricia Research
 Date Submitted: 07/19/2021

Industries & Products	Yes	No
Please indicate if the company is involved in production of or trade in any the following. Select Yes for all options that apply.		
Animal Products or Services		✓
Biodiversity Impacts		✓
Chemicals		✓
Company Explanation Of Disclosure Item Flags		✓
Disclosure Alcohol		✓
Disclosure Firearms Weapons		✓
Disclosure Mining		✓
Disclosure Pornography		✓
Disclosure Tobacco		✓
Energy and Emissions Intensive Industries		✓
Fossil fuels		✓
Gambling		✓
Genetically Modified Organisms		✓
Illegal Products or Subject to Phase Out		✓
Industries at Risk of Human Rights Violations		✓
Marketing of Breastmilk Subsidies	✓	
Nuclear Power or Hazardous Materials		✓
Payday, Short Term, or High Interest Lending		✓
Water Intensive Industries		✓
Tax Advisory Services		✓

Supply Chain Disclosures	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones		✓
Child or Forced Labor		✓
Negative Environmental Impact		✓
Negative Social Impact		✓
Other		✓

Outcomes & Penalties	True	False
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior		✓
Breaches of Confidential Information		✓
Bribery, Fraud, or Corruption		✓
Company Explanation Of Disclosure Item Flags		✓
Company has filed for bankruptcy		✓
Consumer Protection		✓
Financial Reporting, Taxes, Investments, or Loans		✓
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)		✓
Labor Issues	✓	
Large Scale Land Conversion, Acquisition, or Relocation		✓
Litigation or Arbitration		✓
On-Site Fatality		✓
Penalties Assessed For Environmental Issues		✓
Political Contributions or International Affairs		✓
Recalls		✓
Significant Layoffs		✓
Violation of Indigenous Peoples Rights		✓
Other		✓

Practices	True	False
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	✓	
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)		✓
Company Explanation Of Disclosure Item Flags		✓
Company prohibits freedom of association/collective bargaining		✓
Company workers are prisoners		✓
Conduct Business in Conflict Zones		✓
Confirmation of Right to Work		✓
Does not transparently report corporate financials to government		✓
Employs Individuals on Zero-Hour Contracts		✓
Facilities located in sensitive ecosystems		✓
ID Cards Withheld or Penalties for Resignation		✓
No formal Registration Under Domestic Regulations		✓
No signed employment contracts for all workers		✓
Overtime For Hourly Workers Is Compulsory		✓
Payslips not provided to show wage calculation and deductions		✓
Sale of Data		✓
Tax Reduction Through Corporate Shells		✓
Workers cannot leave site during non-working hours		✓
Workers not Provided Clean Drinking Water or Toilets		✓
Workers paid below minimum wage		✓
Workers Under Bond		✓
Other	✓	

Introduction:

For clarity purposes, Nutricia Research BV is neither selling nor marketing/promoting breast milk substitute products.

Nutricia Research BV is a subsidiary of Danone S.A., a multinational company with the mission of bringing health through food to as many people as possible. Nutricia Research BV conducts research to pioneer nutritional solutions, including products that can qualify as breast milk substitutes (BMS). These products are manufactured, sold and marketed by other (commercial) entities of Danone S.A.

As determined by B Lab's independent Standards Advisory Council, companies involved in the marketing of breastmilk substitutes (which is not the case of Nutricia Research BV) 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 Substitutes \("Danone's Policy"\)](#) is applicable to Nutricia Research BV even though Nutricia Research BV's activities are limited to research and not linked to sales, marketing/promotion of covered products. Research conducted by Nutricia Research is in line with ICH-GCP Guidelines, the Declaration of Helsinki and the WHO Code. Furthermore, 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

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

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 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. Danone 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."

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"

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

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 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, metabolise 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".

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).

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

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 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 may 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:

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'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."
- 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 68%, ranking number one in the ATNI – BMS/CF Index 202](#). Nutricia Research BV 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, Danone 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

B Corp Certification - Disclosure Questionnaire Documentation

PROVIDED BY:

Danone Nutricia Research

UPDATED AS OF:

07/19/2021

DISCLOSURE QUESTIONNAIRE CATEGORY	Animal Testing
TOPIC	Nutricia Research BV has a license to conduct animal research in the Netherlands, but most animal research is conducted by their academic partners.
SUMMARY OF ISSUE	<p>Animal research, is conducted in accordance with Danone's applicable policies. These policies state that animal testing can only be conducted in limited circumstances to ensure the safety and efficacy of products. In some cases, these tests are used to understand the mechanism of action of Danone's innovations or are part of the safety assessments required by national regulatory authorities for pre-market approvals. Animal testing is sometimes required to establish ingredient safety under FDA Generally Recognized as Safe processes, or other regulatory requirements. Animal testing may also be required as part of the preparation-phase to establish efficacy before initiating the clinical testing process.</p> <p>Danone mainly outsources required animal testing via academic partnerships, and some CRO-studies for FDA and EFSA. The Animal Welfare Body of Danone Nutricia Research reviews proposals to conduct animal testing, and screens for TripleR opportunities (Replace animal testing, Reduce the number of animals being used, and Refine the procedures), Humane End Points etc. The Research Agreements of studies that involve animals, contain a specific Animal Welfare clause where compliance to regulations, guidelines, and animal welfare standards is described, as well as mandatory reporting and evaluation of animal welfare. Additionally, under Danone policy, vendors must be evaluated through Danone third party vetting procedures and contracts require vendors to agree to Danone's Sustainability Principles and Code of Conduct for business partners. Only a few studies per year are conducted under the Ethical License of Danone Nutricia Research (NL). The Ethical License is obtained from the national competent authority, after independent Ethical Review, and is fully compliant to the EU- Directive for the protection of animals used for scientific purposes (Directive 2010/63/EU). The Animal Welfare Body reviews the experimental design, TripleR opportunities, refinement of housing, care and procedures, and only approves the detailed protocols if a statistical analysis plan is in place that is approved by a biostatistician.</p>
SIZE/SCOPE OF ISSUE (e.g. \$ financial implication, # of individuals affected)	Animal research cannot always be avoided in the process of investigating the underlying biological mechanisms the body uses to process certain nutrients or the efficacy and safety of nutritional products. As the whole development process entails Danone's own scientific research as well as at academic institutes and suppliers, it is not possible to provide percentages of products that might have at some point used data from animal models.
IMPACT ON STAKEHOLDERS	The use of animals is a general concern within society, and consumers are therefore (to a certain extent) interested to know if animal research was involved. It is important to note that approx. 70% of the experiments in the EU are categorized as causing mild discomfort, and that strict guidelines and standards are in place to minimize discomfort and weigh the discomfort versus the aim of the study and future (health) benefit of the results.

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DISCLOSURE QUESTIONNAIRE CATEGORY	Animal Testing Cont'd
IMPLEMENTED MGT PRACTICES	<p>Danone always challenges the need to do animal testing and, where possible, uses available approaches based on alternative methods. They consult external experts and ethical committee review, to ensure the right approach. Where no other options are available, animal testing is carried out but only within a very strict framework. All animal tests comply with mandatory guidelines to take into consideration animal welfare and protocols recommended by authorities and NGOs (WHO, OIE, ILSI, etc.). Danone apply the strict existing standards for the protection and care of animals used for scientific purposes, based on the European Union guidelines and compliant to local regulations. They are also extending these standards as referential to all collaborations in other countries.</p> <p>Danone collaborates with academic institutes, using the available expertise, sharing interests and data to increase quality and reduce the number of animals. Their policy is to publish in peer reviewed journals, making the research visible and transparent and making it possible for others to leverage the methods and data. Furthermore, they aim to answer all inquiries related to animal research and are engaged in several initiatives related to alternatives to animal testing.</p> <p>They have a Public Disclosure Policy, and related process, and strive for compliance to the ARRIVE* guidelines [*Animal Research: Reporting of In Vivo Experiments]. Originally published ARRIVE in PLOS Biology, June 2010 available at: http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1000412, and manuscripts containing data of animal models are screened for this.</p> <p>To foster progress in Triple R research, Danone take part in a number of concrete initiatives that include participation in several research-projects in which alternative methods are developed and validated, and on-going collaboration with the 3R center in the Netherlands. In addition, Danone plays a key role in the ILSI Europe multi-stakeholder task force: Alternatives to Animal Testing in Food Safety, Nutrition and Efficacy Studies.</p> <p>Some of Danone's initiatives to foster Replacement models include:</p> <ul style="list-style-type: none"> - Active participation in the Netherlands in "SLIM", a multi-stakeholder project under a public private consortium focusing on the development and legal approval of alternative methods. This project led to the development of a robust and sensitive in vitro assay (RBL) to test the safety of cow's milk hydrolysates (important for infants with cow's milk allergy). - Development with TNO in the Netherlands of "TIM systems" which simulate the gastrointestinal tract from stomach to small intestine. Danone Nutricia Research also set up a project on the use of these models with the University of Clermont-Auvergne in France. - Development of an in vitro model, the GIDS [Gastro-Intestinal Digestive System] at Danone Nutricia Research to simulate upper gastrointestinal tract conditions. The use of this in vitro model of digestion allows significant reduction of animal testing in this area of research. The system is constantly optimized to grow-up its field of application. - Routine use of in vitro gut fermentation models in research projects, such as SHIME (Simulator of Human Intestinal Microbial Ecosystem). Danone Nutricia Research has also developed a model system to simulate the colonic fermentation (COGAM). This system is used to monitor the impact of food on microbiota profile and function such as production of metabolites or gas.

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DISCLOSURE QUESTIONNAIRE CATEGORY	Animal Testing Cont'd
IMPLEMENTED MGT PRACTICES CONT'D	<ul style="list-style-type: none"> - Realisation of the Nutrition Clinical Research Unit (NCRU) in the Danone Nutricia Research innovation center. This facility provides new opportunities to gather insights to pioneer nutritional discoveries. The high standard clinical studies with food and nutrients in volunteers will facilitate earlier translation into concepts for specific human application. - Participation in Create-2-Solve: an initiative supported by the Dutch Government and an NGO to develop alternatives to animal research models, as part of the program: 'More Knowledge with Fewer Animals', of which the Dutch Ministry of Agriculture, Nature and Food Quality is the commissioning organization. - Engagement in several academic partnerships where currently development and validation of human organoids, human cell-lines, and organ-on-a-chip is ongoing. - Investment in in silico methods and Systems Biology as part of our research-portfolio.
REPORT	<p>Danone Position Paper on Animal Testing: https://www.danone.com/content/dam/danone-corp/danone-com/about-us-impact/policies-andcommitments/en/2016/2016_09_20_AnimalTesting2016PositionPaper.pdf</p>

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DISCLOSURE QUESTIONNAIRE CATEGORY	Penalties regarding labor issues (including supply chain)
ISSUE DATE	Between November 2016 & December 2017 Penalty date: September 2019
TOPIC	Penalty pertaining to breach of statutory maximum daily working time
SUMMARY OF ISSUE	<p>Between November 2016 and December 2017, 32 different individuals exceeded daily or weekly working hours, resulting in a total of 53 breaches of maximum hours at the Danone Research site. 44 were breaches of daily maximum hours and 9 were breaches of weekly maximum hour.</p> <p>As a result of this, in September 2019, Danone Research received an administrative penalty notification issued by the « Direction Régionale des Entreprises, de la concurrence, de la consommation, du travail et de l'emploi d'Ile de France.</p>
SIZE/SCOPE OF ISSUE (e.g. \$ financial implication, # of individuals affected)	The number of employees that exceeded maximum working hours, represented 4.9% of the total staff at the Danone Research site at the time.
IMPACT ON STAKEHOLDERS	Exceeding maximum statutory working times may pose risks to the health and safety of concerned employees.
RESOLUTION	The total penalty amount of 20,750 Euros was paid by Danone Research to the pertinent government agency.
IMPLEMENTED MGT PRACTICES	<p>Management up to the highest levels of hierarchy within Danone Research were informed about this penalty. They connected with their respective teams to ensure compliance with the maximum statutory working time.</p> <p>Different physical controls means have been implemented to track attendance times. KPIs have been implemented and are shared with HR managers to be presented in teams and operational committees.</p> <p>Compliance with maximum statutory working time has also been included as one of the criteria to determine the quantum of employee profit-sharing within Danone Research.</p>