



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

PROVIDED BY:

Nutricia North America

UPDATED AS OF:

07/01/2020

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		✓
Monoculture Agriculture		✓
Nuclear Power or Hazardous Materials		✓
Payday, Short Term, or High Interest Lending		✓
Water Intensive Industries		✓
Other		✓

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		✓

Other Disclosures	Yes	No
		✓

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		✓



B Corp Certification - Disclosure Questionnaire Documentation

PROVIDED BY:

Nutricia North America

UPDATED AS OF:

07/01/2020

DISCLOSURE QUESTIONNAIRE CATEGORY	Animal Testing
TOPIC	Nutricia North America produces specialised nutrition products for medical use that are legally required to be tested on animals for sale in certain jurisdictions.
SUMMARY OF ISSUE	<p>Research for Nutricia North America, as part of Danone, is conducted through the Netherlands based Danone Nutricia Research function and in accordance with Danone's applicable policies, who only conduct animal testing in limited circumstances when deemed necessary 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 clinical testing process to establish efficacy.</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 to investigate the biological mechanisms behind 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 STAKEHOLDER(S)	Animal testing and experimentation is widely used to develop new medicines and to test the safety of other products. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways.

<p>IMPLEMENTED MGT PRACTICES</p>	<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. - 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.
<p>REPORT</p>	<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>