

Sanofi CHC Germany

Disclosure Report Date Submitted: October 25th, 2023

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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 that B Lab deems relevant for public stakeholders, then, as a condition of their certification, the company must:

- Be transparent about details of 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 practices are in place to avoid similar issues from arising in the future, when necessary.

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

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to a background check 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

Industries and Products

Yes No Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that **Animal Products or Services** $\boxed{}$ **Biodiversity Impacts Chemicals** $\overline{\mathbf{A}}$ **Disclosure Alcohol Disclosure Firearms Weapons** $\boxed{}$ **Disclosure Mining** $\boxed{}$ **Disclosure Pornography** $\boxed{}$ **Disclosure Tobacco** $\boxed{}$ **Energy and Emissions Intensive** $\boxed{}$ Industries Fossil fuels \square Gambling **Genetically Modified Organisms** $\overline{\mathbf{A}}$ Illegal Products or Subject to $\overline{\mathbf{A}}$ **Phase Out** Industries at Risk of Human \square **Rights Violations Monoculture Agriculture** \square **Nuclear Power or Hazardous** $\overline{\mathbf{A}}$ **Materials** Payday, Short Term, or High **Interest Lending** Water Intensive Industries \square **Tax Advisory Services**

Outcomes & Penalties

	Yes	No
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		\checkmark
Breaches of Confidential Information		V
Bribery, Fraud, or Corruption		V
Company has filed for bankruptcy		V
Consumer Protection		V
Financial Reporting, Taxes, Investments, or Loans		N
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)		N
Labor Issues		V
Large Scale Land Conversion, Acquisition, or Relocation		K
Litigation or Arbitration		
On-Site Fatality		V
Penalties Assessed For Environmental Issues		V
Political Contributions or International Affairs		K
Recalls		V
Significant Layoffs		V
Violation of Indigenous Peoples Rights		N
Other		\checkmark



Practices

	Yes	No
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	\checkmark	
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)		N
Company prohibits freedom of association/collective bargaining		V
Company workers are prisoners		\checkmark
Conduct Business in Conflict Zones		
Confirmation of Right to Work		V
Does not transparently report corporate financials to government		\searrow
Employs Individuals on Zero-Hour Contracts		<
Facilities located in sensitive ecosystems		\vee
ID Cards Withheld or Penalties for Resignation		N.
No formal Registration Under Domestic Regulations		V
No signed employment contracts for all workers		V
Overtime For Hourly Workers Is Compulsory		V
Payslips not provided to show wage calculation and deductions		V

	Yes	No
Sale of Data		\checkmark
Tax Reduction Through Corporate Shells		V
Workers cannot leave site during non-working hours		V
Workers not Provided Clean Drinking Water or Toilets		V
Workers paid below minimum wage		\vee
Workers Under Bond		\checkmark
Other		\checkmark

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		V
Child or Forced Labor		\checkmark
Negative Environmental Impact		V
Negative Social Impact		\checkmark
Other		✓



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Sanofi CHC Germany is a subsidiary of Sanofi CHC that manufactures and sells consumer healthcare products. Sanofi CHC Germany does not perform research and development activities (eg. new drug molecules) that require the use of animal testing. Due to the nature of the portfolio of established products, animal testing is only performed in rare situations when required by Regulatory Authorities due to safety concerns and no alternative methods can be applied.
Summary of Issue	As a company that manufactures, and sells pharmaceutical products, the company is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products. As a subsidiary of Sanofi CHC, Sanofi CHC Germany sells consumer healthcare products which have already been proven to be safe and effective and therefore do not require the generation of new animal safety data for their registration procedure.
	In sum, Sanofi CHC Germany would only perform animal studies in rare situations when required by Regulatory Authorities to evaluate and assess major safety concerns and if no alternatives are available including if literature/data was unavailable for the study endpoints needed, and if performing human testing was unethical.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	Sanofi CHC Germany has not conducted any animal testing on the products in the Sanofi CHC Germany portfolio over the past 5 years. However, the company sells healthcare products that rely on animal data generated previously to demonstrate the efficacy and safety of the treatment and/or to satisfy Regulatory Authorities requests.
Impact on Stakeholders	Animal testing is a regulatory requirement to develop and test the safety of new drug molecules. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways. Therefore, the extent of animal safety testing is reduced to a minimum during the development of new molecules. As already mentioned Sanofi CHC Germany does not develop new drug molecules and would only perform animal testing in rare situations when required by Regulatory Authorities e.g. due to safety.
Management Practices	Sanofi CHC Germany does not carry out animal testing at a local level. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only:
	 - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement).
	Sanofi has animal ethics committees with principles to ensure impartiality and



	independence of the ethical review.
	Sanofi CHC rarely authorizes animal testing and only when the regulatory respective scientific merit is established and under strict ethical oversight. If animal testing is authorized, Sanofi CHC monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations).
	External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use programs of external partners on a regular basis and approve those that comply with Sanofi standards.
	In addition to the legal obligations, Sanofi has set internal standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is assessed by Sanofi professionals to ensure the consistency of the animal care. Further information can be found in the Sanofi Animal Protection Factsheet and Animal Protection Policy (links below).
	Sanofi is also a signatory of the pharmaceutical industry declaration on animal housing and use, Marseille Declaration (see link below)
	External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
Report	Sanofi Animal Protection Factsheet Sanofi Policy on Animal Protection Signed Marseille Declaration



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Topic	Chemical Intensive Industries
Summary of Issue	Sanofi CHC Germany operates in the pharmaceutical industry which has been recognized as a chemical-intensive industry. The company is not involved in the production, operation, trade, or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC) under REACH. At the Cologne site, the company uses SVHC lab chemicals for quality control purposes. While the company does not use SVHC, in the laboratory, the company tries to reduce the amount/potency of chemicals by always looking for alternative methods first. This is in line with German best practices in safety management, called STOP: S - Substitution T - Technical protective measures O - Organizational protective measures P - Personal protective measures
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	The use of chemicals for quality control purposes at the Cologne site is approximately 1 ton/year and does not include any SVHC.
Impact on Stakeholders	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Sanofi CHC Germany has not experienced any incidents and/or fines related to environmental or worker health impacts for chemical use.
Management Practices	All chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. The company regularly tests the wastewater and shares result reports with authorities periodically, in line with German regulation and permits. At the global level, the company has implemented a program to identify substances of potential future concern in the company's formula and plan their substitution or removal whenever possible from a technical or regulatory standpoint. The program includes a list of materials or substances to be banned, avoided, or restricted in Sanofi CHC products. Moreover, Sanofi CHC Germany has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic and volatile organic compounds. All product formulas are approved under the relevant health authorities' requirements, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products



remains adequate for the safe and intended use of consumers.

At the local level, the company does not conduct an assessment and comparison with other companies regarding chemical use.



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Topic	Water Intensive Industries
Summary of Issue	Sanofi CHC Germany operates in the pharmaceutical industry which is recognised as a water-intensive industry due to manufacturing and cleaning processes. The company's manufacturing site is in Cologne, Germany. Although the region is not a water stressed area, the company is working on a water use reduction plan. The company's manufacturing plant sources 100% of its water from the municipal water network.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	In the previous fiscal year, 100% of Sanofi CHC Germany was derived from the production of self-medication medicines/drugs, food/dietary supplements, and cosmetics Sanofi CHC Germany has a water intensity of 0.80 liter per unit of product produced for its standard manufacturing processes.
Impact on Stakeholders	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water use is not appropriately managed. The company sources 100% of its water from the municipal water network. The main stakeholders affected are other water users in the region, such as local water authorities & regulators, residents, other industrial plants, farmers, and the local biodiversity.
Management Practices	The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and management. Globally, Sanofi CHC has the target of reducing water consumption by 20% by 2030, with 2019 levels as a benchmark. Sanofi CHC's sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed and defining a strategy aligned with local communities to properly manage the watershed the company relies on.