



Lab
Global

ESTEVE

Disclosure Report

Date Submitted: November 27th, 2025



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:

- 1) 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 apply.		
Animal Products or Services	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Biodiversity Impacts	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Chemicals	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Disclosure Alcohol	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Disclosure Firearms Weapons	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Disclosure Mining	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Disclosure Pornography	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Disclosure Tobacco	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Energy and Emissions Intensive Industries	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Gambling	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Genetically Modified Organisms	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Illegal Products or Subject to Phase Out	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Industries at Risk of Human Rights Violations	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Monoculture Agriculture	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Nuclear Power or Hazardous Materials	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Payday, Short Term, or High Interest Lending	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Water Intensive Industries	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Tax Advisory Services	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Breaches of Confidential Information	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Bribery, Fraud, or Corruption	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Company has filed for bankruptcy	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Consumer Protection	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Financial Reporting, Taxes, Investments, or Loans	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Labor Issues	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Large Scale Land Conversion, Acquisition, or Relocation	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Litigation or Arbitration	<input type="checkbox"/>	<input checked="" type="checkbox"/>
On-Site Fatality	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Penalties Assessed For Environmental Issues	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Political Contributions or International Affairs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Recalls	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Significant Layoffs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Violation of Indigenous Peoples Rights	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>	<input checked="" type="checkbox"/>



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

	Yes	No
Sale of Data	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Tax Reduction Through Corporate Shells	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Workers cannot leave site during non-working hours	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Workers not Provided Clean Drinking Water or Toilets	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Workers paid below minimum wage	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Workers Under Bond	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child or Forced Labor	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Negative Environmental Impact	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Negative Social Impact	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>	<input checked="" type="checkbox"/>



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Chemical Intensive industry

Esteve is involved in the production/sale of products, or is part of an industry that can potentially be classified as chemical intensive, meaning that they are more likely to have significant impacts on the environment, such as pollution of air, land, and water, as well as potential human health risks to those exposed to harmful chemicals if the use and disposal of chemicals are not properly managed. Certified B Corps are required to make transparent their involvement in such activities or industries.

For more information about the company's practices regarding this topic, please visit the company's webpage/ sustainability report, accessible [here](#).



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Energy and Emissions Intensive industry

Esteve is involved in the production/sale of products, or is part of an industry that can potentially be classified as energy and emission-intensive, meaning that they are more likely to have significant impacts on the environment based on their carbon emissions associated with their operations and their contribution to climate change. Certified B Corps are required to make transparent their involvement in such activities or industries.

For more information about the company's practices regarding this topic, please visit the company's webpage/ sustainability report, accessible [here](#).



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Water Intensive industry

Esteve is involved in the production/sale of products, or is part of an industry that can potentially be classified as water intensive, meaning that they are more likely to have significant impacts on the environment, such as water stress or depletion of local water sources if water use is not appropriately managed. Certified B Corps are required to make transparent their involvement in such activities or industries.

For more information about the company's practices regarding this topic, please visit the company's webpage/ sustainability report, accessible [here](#).



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Esteve reported conducting 6 voluntary recalls in the past five years, representing 3.38% of the company's products for the same period. When a product is recalled, various stakeholders such as customers, suppliers, investors, commercial partners, and local communities may face negative impacts, including health and safety risks, financial losses, loss of trust, damage to credibility, and other inconveniences. Certified B Corps must make their recalls transparent under their B Corp Profile.

For more information about the company's practices regarding this topic, please visit the company's webpage/ sustainability report, accessible [here](#).



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Animal Testing

Disclosure Questionnaire Statement	
Topic	The company is required to undergo mandatory animal testing by law.
Summary of Issue	ESTEVE is a pharmaceutical company that develops programs focused on advanced clinical phases and preclinical non-clinical phases that are required to be tested on animals by law in the markets where they operate. ESTEVE engages with third-party testing facilities; all testing activities, including animal studies, are outsourced to Contract Research Organizations (CROs). Animal testing is mandated by law in several regulated markets as part of the drug development and approval process. Regulatory bodies such as the European Medicines Agency (EMA) in the European Union, the U.S. Food and Drug Administration (FDA), the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, and other national authorities in countries like China, Canada, and Australia enforce these regulations. In Spain and the EU, both ESTEVE and the CROs must comply with national and European legislation on animal protection. This includes Law 32/2007, Law 6/2013, Royal Decree 53/2013, and Royal Decree 118/2021, along with related orders that implement Directive 2010/63/EU. These regulations enforce the 3Rs principles (Replacement, Reduction, and Refinement), require ethical evaluation, authorization, and personnel training. Additional guidance is provided by the European Convention of Strasbourg and EU recommendations regarding the care and housing of experimental animals.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	In the previous fiscal year, 30% of the company's products, including prescription medicines that are not legally classified as generic and medical devices, underwent animal testing. Previously, it was estimated that 35% of the company's products underwent animal testing.
Impact on Stakeholder(s)	Animal testing and experimentation is also used to develop new pharmaceutical products 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.
Implemented Management Practices	ESTEVE has established an animal welfare policy for activities related to animal testing conducted by contract research organizations (CROs), manufacturers, and partners. This policy requires compliance with various regulations, including Good

Clinical Practices (GCP), Good Manufacturing Practices (GMP), Regulation (EU) No. 536/2014, and relevant guidelines from the International Conference on Harmonization (ICH). ESTEVE also ensure the compliance of S1A, S1B, S1C, S1C(R): Carcinogenicity Studies, S2A, S2B: Genotoxicity Testing, S3A, S3B: Toxicokinetic and Pharmacokinetics, S4A: Chronic Toxicity Testing, S5A, S5B: Reproduction Toxicity, S6: Biotechnology-Derived Pharmaceuticals, S7A: Safety Pharmacology Testing, S7B: Assessment of QT Interval Prolongation, S8: Immunotoxicity, S9: Anticancer Pharmaceuticals, S10: Phototoxicity, M3: Nonclinical Safety Studies, and M7: Mutagenic Impurities. Before signing a contract with a Contract Research Organization (CRO), audits are performed to assess study performance. Additionally, the CRO is subject to inspections by authorities, which typically occur every 2 to 3 years. CROs must be licensed and accredited, and their facilities are subject to inspections by the relevant authorities. ESTEVE programs focus on late-stage phases and do not involve the clinical testing conducted by their third parties; therefore, the company does not retain documentation or evidence related to audits from those earlier stages during preclinical testing.

Although ESTEVE does not perform preclinical studies and therefore does not carry out animal testing itself, the company ensures that its collaborators have the necessary controls in place and comply with ethical and regulatory standards. ESTEVE primarily works with third parties that are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).

The policy encourages the exploration of alternatives to animal testing while maintaining scientific integrity and supports the 3Rs principles: Replace, Reduce, and Refine. It emphasizes the respectful treatment of animals, aiming to minimize their pain and stress, and ensures that any alternatives used are scientifically valid according to regulatory standards. When animal studies are legally required, ESTEVE strives to replace animal testing with non-sentient alternatives (e.g., in vitro studies), reduce the number of animals used to the minimum required, and refine studies involving animals to further minimize pain and distress. The policy also highlights the importance of species-specific needs and advocates for the



	<p>use of appropriate methods for sedation or anesthesia when necessary, as well as the retirement of animals when appropriate.</p> <p>Furthermore, Esteve's Third-Party Code (section 5.11) reinforces the 3R principles. The selection and qualification of CROs follow Esteve's Standard Operating Procedures (SOPs) for Strategic Sourcing and Contract Management. This includes risk assessment and pre-contract audits to ensure compliance with Good Laboratory Practice (GLP) guidelines, ethical standards, and relevant regulatory requirements.</p> <p>All stakeholders are informed about and aligned with this policy, which is reinforced in the ESTEVE Code of Conduct. This code outlines the obligations of employees and stakeholders to uphold animal welfare standards.</p>
Report	ESTEVE'S Commitment on Animal Welfare ESTEVE'S Third-Party Code