Compliance & Risks

ULTIMATE GUIDE TO

Product Compliance

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Table Of Contents

1. Introduction

In an increasingly globalized and regulated marketplace, product compliance has become a critical concern for global manufacturers. Product compliance refers to the process of ensuring that a product meets all the regulatory requirements and standards relevant to its market.

This guide aims to provide you with a comprehensive overview of product compliance - covering key concepts, strategies, and best practices to navigate the complex landscape.

2. Understanding Product Compliance

2.1 WHAT IS PRODUCT COMPLIANCE?

To launch a product to market, companies need to ensure their product meets all requirements set by the parliaments and regulatory bodies in the country/market it plans to sell in. This process is coined as "Product Compliance".

Having said that, it's also important to remember that product compliance isn't just about safety. It also includes labeling and packaging, as well as data security and privacy laws to name a few for those more connected products on the market.

Product compliance aims to ensure that consumers are safe from harm - different

Governments enforce laws, governing bodies propose regulations to help abide by these laws, and various organizations release standards that act as a yardstick to help stay compliant with a set of regulations. In short, manufacturers are responsible for ensuring their products are safe for people to use.

legislative bodies have different rules depending on the country or region they're in.

2.2 PRODUCT COMPLIANCE - OBJECTIVES

The objective of product compliance is to make sure that consumers are safe from harm. To that effect, different legislative bodies have different rules depending on the country or region they're in.

1. **Market Access:** To facilitate products to be sold in target markets.
2. **Legal Obligations:** To fulfill legal requirements set by regulatory authorities.
3. **Consumer Safety:** To ensure that products are safe to use.
4. **Reputation:** To maintain trust & brand reputation.
5. **Risk Mitigation:** To reduce the risk of compliance surprises & impact on revenue generation.

Read our What is Product Compliance blog if you are looking for a quick crash course.

2.3 WHO IS RESPONSIBLE FOR PRODUCT COMPLIANCE?

While the exact distribution of compliance responsibilities varies by company, Product Compliance is often a core responsibility of,

1. **Compliance Officer -** responsible for overseeing compliance within an organization, and ensuring compliance with laws, regulatory requirements, policies, customer/internal requirements, and procedures.

2. **Product Compliance Team/Manager/, Regulatory Affairs Team/Manager -** responsible for ensuring that all products meet their legal requirements and can be marketed without objections from the authorities.

| What does a Compliance Officer do?	What does a Product Compliance Manager do?
Develop, implement & manage acompany's compliance program.	Identify all relevant regulations & standards for the products sold by the company.
Plan, implement & oversee risk-relatedprograms.	Interpret regulations & define compliance requirements - scope of the company's own permits, certifications, and laboratory tests and how these are carried out.
Create & coordinate reports for compliance issues.	Work out the rules for checking documents from suppliers against the company's own standards.
Develop an organization's compliance communications.	Align stakeholders from neighboring teams -product, quality management, logistics, marketing, procurement, sales, etc. - to collaborate on product compliance requirements.
Coordinate & schedule necessary compliance training for employees.	Procure evidence to demonstrate product compliance.

2.4 THE REGULATORY LANDSCAPE IN 2023

The regulatory landscape in 2023 - especially with ESG regulations in action, has taken a step forward from being dynamic - to being a living area with changes happening almost every other day.

Companies face increasingly complex and changing requirements influenced by globalization, technological advancements, and environmental concerns. Staying up-to-date with these regulations is essential to compliance.

Since 2016, there has been an 84% growth in global regulations (See below, Figure 1: Source, C2P Platform by Compliance & Risks).

84% Growth in Global Regulations in 7 years

Source: C2P by Compliance & Risks
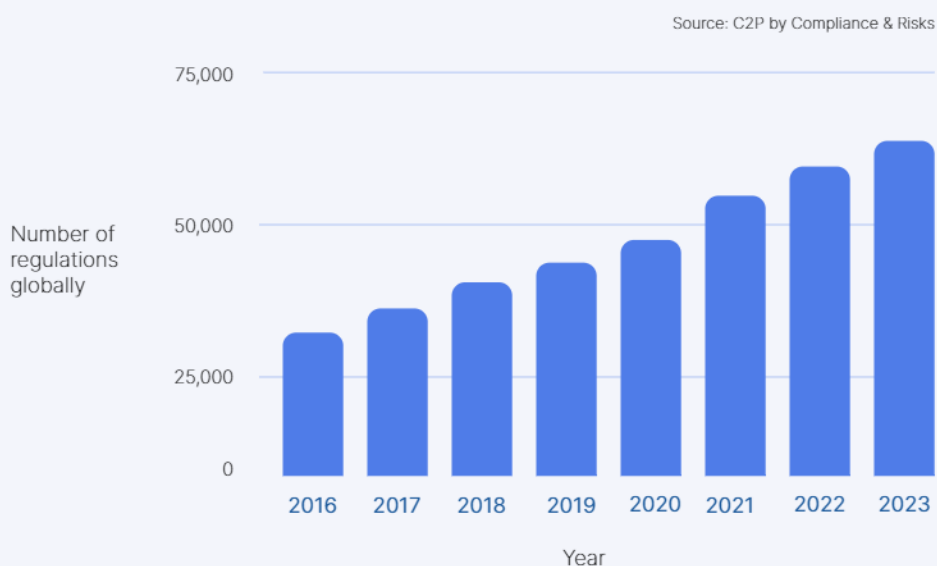
3. Key Regulations & Standards

3.1 INDUSTRY-SPECIFIC STANDARDS

Each industry has its own specific standards that must be followed. A few examples include,

3.1.1 MEDICAL DEVICES:

➡ EU Medical Devices, Regulation (EU) 2017/745

➡ EU In Vitro Diagnostic Medical Devices, Regulation (EU) 2017/746

➡ FDA Guidance for Industry and FDA Staff, Medical Device Reporting for Manufacturers 2016

➡ EU: Publication of Harmonised Standards for Medical Devices, Commission Communication, 2017/C 389/03, Harmonised Standards for Directive 93/42/EEC

➡ UK: BS EN IEC 60601-2-20:2020 Medical electrical equipment, 2020

A few related blogs,

📖 Regulatory Trends in Medical Devices

📖 EU Adopts Restriction of Intentionally Added Microplastics

📖 European Commission Publishes MDR and IVDR Factsheet for Non-EU/EEA Countries

📖 Enhancing Medical Device Safety: New Post-Market Surveillance Requirements in the UK

📖 Keeping Pace with Change: Recent Regulatory Updates Shaping Medical Device Compliance

Check out Compliance & Risks'
Solutions for the Medical Devices industry.

3.1.2 APPAREL:

→ EU Safety of Toys, Directive 2009/48/EC

→ EU Persistent Organic Pollutants (POPs) Regulation (EC) No. 850/2004

→ EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) 1907/2006

→ EU Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU

→ EU: Packaging and Packaging Waste Directive 94/62/EU

A few related blogs,

📖 EU To Revise Textile Fiber ID Regulation

📖 Greenwashing In The Fashion Industry: Why Transparency Is Key For Sustainable Brands

📖 Sustainability In Apparel: France's Triman Logo

📖 EU Seeks Stakeholder Collaboration For 'Textiles Ecosystem Transition Pathway'

📖 Mastering Sustainability Reporting with IFRS S1: IFRS Webinar Recap

Check out Compliance & Risks' Solutions for the Apparel industry.

3.1.3 CONSUMER ELECTRONICS:

→ EU: Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU (and EU Member State implementations)

→ EU: Framework for Energy Efficiency Labelling, Regulation (EU) No 2017/1369

→ EU: Energy Labelling of Smartphones and Slate Tablets, Regulation No. 2023/1669

→ EU: Batteries and Accumulators and Waste Batteries and Accumulators Directive 2006/66/EC

→ EU: Low Voltage Electrical Equipment, Directive 2014/35/EU

A few related blogs,

📖 Connected Compliance: Top Consumer Electronics Queries – July 2023

📖 Key Overview of the Revised Swiss Personal Data Protection Act

📖 What's New in Consumer Electronics Product Compliance?

📖 New Rules on Phones and Tablets Enable Sustainable Choices by Consumers

📖 Consumer Electronics: Key Updates on Chargeability, Accessibility, Removability & Labeling

Check out Compliance & Risks Solutions for Consumer Electronics industry.

3.1.4 HOUSEHOLD APPLIANCES:

→ USA: Consumer Product Safety Act, 15 U.S.C. 2051-2084, 1972, As Amended 1994

→ EU: General Product Safety, Regulation (EU) 2023/988

→ United States (US): FCC Radio Frequency Devices Regulations, 47 CFR Part 15

→ European Union (EU): Electromagnetic Compatibility, Directive 2014/30/EU

→ EU: Energy Labelling of Smartphones and Slate Tablets, Regulation No. 2023/1669

→ EU: Ecodesign for Energy Related Products (ErP), Directive 2009/125/EC

A few related blogs,

📖 Climate Disclosure Obligations In The EU, USA And Beyond

📖 Navigating the New EU Machinery Safety Requirements: What's on the Horizon?

📖 Chemicals Quarterly – Q3 Regulatory Update 2023

📖 Climate Disclosure Obligations In The EU, USA And Beyond

📖 Spotlight On The S in ESG – Upcoming EU Rules On Supply Chain Transparency, Due Diligence & Reporting On Social Matters

Check out Compliance & Risks Solutions for the Household Appliances industry.

3. 2 REGIONAL & INTERNATIONAL REGULATIONS

Different regions have distinct regulatory frameworks. Some notable examples include:

BLOG │ 4 MINS READ

FDA (U.S.)

Ensures the safety and efficacy of food, drugs, and medical devices.

Check out a related blog - US FDA Drafts Guidance on Medical Device Software Function

BLOG │ 5 MINS READ

EU CE Marking

Certifies that products meet European Union safety standards.

Check out a related blog - Indefinite Extension to the Use of CE Marking Announced for UK Businesses

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BLOG | 7 MINS READ

RoHS (EU)

Restricts the use of certain hazardous substances in electrical and electronic equipment.

Check out a related blog - RoHS Impact Assessment Published: Key Findings & Recommendations

BLOG

REACH (EU)

Addresses the registration, evaluation, authorization, and restriction of chemicals.

Check out a related blog - REACH Compliance Solutions

BLOG | 8 MINS READ

Triman Logo (France)

Article 17 of the AGEC Law states that all household products, including cosmetic products, must bear France's Triman logo and sorting instructions (Info-Tri) for each packaging element.

Read our a recent blog on From Obligation to Opportunity: Harnessing EPR And The Triman Logo In France's Circular Economy

BLOG | 10 MINS READ

ESG Regulations (EU)

As the global community becomes increasingly aware of the impact of human activity on the environment, companies are facing mounting pressure to implement sustainable and socially responsible practices. In response, governments and regulatory bodies are introducing a wave of new environmental, social, and governance (ESG) regulations aimed at promoting sustainable business practices and protecting the planet. These regulations cover a wide range of issues, from carbon emissions and energy efficiency to worker safety and human rights.

Check out the full list in our blog - ESG Regulations: What's Coming Next?

Battery Passport Regulation (EU)

To be listed in the European market, each battery must have a unique battery passport and responsibility will be on the economic operator placing the battery on the market to ensure that the data included in the battery passport is accurate, complete, and up-to-date.

Check out a recent blog - EU Battery Passport: The Digital Battery Passport in the New EU Draft Battery Regulation

Green Dot Regulations

The Green Dot is one of the most widely used recycling symbols on packaging. It indicates that the producer of the packaging has contributed financially to the recycling of that packaging.

Read our recent blogs on updates in France & Spain, French Court Revokes Restrictions On The Green Dot Symbol Green Dot Compliance Requirements for Packaging Labeling in Spain

PFAS Regulations

Various laws, policies, and regulations have been implemented in the United States (U.S.) and the European Union (EU) to restrict PFAS use and reduce exposure.

Read our whitepaper: A Snapshot of US State-Level Regulatory Developments Restricting or Prohibiting PFAS in Consumer Products in 2023

4. Product Compliance Challenges

4.1 REGULATORY OVERLOAD

The ever-expanding landscape of local & global regulations, standards, and compliance requirements increases the complexity and costs of running successful compliance programs. To thrive in this environment, manufacturers must adopt proactive strategies, leverage technology, and stay abreast of evolving regulations to ensure products meet safety, quality, and environmental standards while maintaining market competitiveness.

4.2 LACK OF A SINGLE SOURCE OF COMPLIANCE TRUTH

The absence of a single source of information for compliance efforts fosters confusion and frustration. We often hear, *"It's a little bit like drinking from a water hose with so much information that's coming at you."* Having a consolidated solution that you can rely on helps improve decision-making for compliance processes and in turn, boost efficiency.

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4.3 FORWARD PLANNING & RISK MANAGEMENT

With the bulk of regulatory changes, it is very difficult to be proactive and plan for the future. Organizations across the globe are trying to move their compliance processes from being reactive to being proactive to facilitate better planning & risk management.

4.4 COMMUNICATING & MANAGING CHANGE

'Zero Surprises' is a tough compliance motto to chase with the dynamic nature of the regulatory landscape. Robust communication is needed to ensure all stakeholders collaborate towards managing a regulatory change and to enable efficient collaboration towards ensuring there are no last-minute compliance surprises impacting revenue & market access.

Check our recent webinar - Workings of A 'Zero Surprise' Compliance Policy to know more.

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5. Product Compliance Strategies

5.1 PRODUCT COMPLIANCE BY DESIGN

Integrating compliance considerations into product design from the outset. This reduces the need for costly redesigns & ensures compliance is a part of the product's DNA.

Benefit — Ensures compliance is a part of the product's DNA

5.2 RISK ASSESSMENT & MITIGATION

This approach helps identify potential compliance risks early & develop strategies to mitigate them. Regular risk assessments help in proactive decision-making.

Benefit — Helps in proactive decision-making

5.3 SUPPLY CHAIN MANAGEMENT

Ensuring that your suppliers and partners also adhere to compliance standards. Supply chain transparency is essential for overall product compliance.

Benefit

Helps supply chain transparency - essential for overall product compliance

5.4 COMPLIANCE TESTING & CERTIFICATION

Conducting thorough testing & certifications from recognized bodies when applicable. Certifications provide assurance to regulators & customers.

Benefit

Helps provide assurance to regulators & customers

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6. ESG & Product Compliance

While 'Product' compliance should not be the 'only' focus of a product manufacturer - there are a few actions that the product compliance team can take to assist towards the company's overall ESG strategy -

6.1 REVIEW PRODUCT PORTFOLIO

Given the way ESG obligations have arisen in this area, many companies are not fully aware of new obligations that may apply to their product portfolio. Companies should track and then review the application of new legislation to their existing product portfolios.

6.2 BE SELECTIVE WITH SUPPLY CHAIN

Although difficult to balance with competing lack of supply of relevant products in some areas, companies should require any new partner to complete thorough and comprehensive onboarding and include protective contractual clauses within any supply agreements to ensure ESG obligations

imposed on companies are requirements suppliers need to adhere to also.

Regular and thorough review processes should be implemented to monitor supply chain compliance with these obligations. Companies could consider requiring declarations from the supply chain throughout the lifetime of their supply.

6.3 CONSIDER ALTERNATIVE MATERIALS & PRODUCTION MECHANISMS

Scrutiny is likely to be imposed on certain materials, such as plastics and single-use items. Companies should consider whether they are able to find long-term alternatives to reduce the use of these highly taxed and regulated products. Similarly, the reduction of the use of natural resources during production should be considered. Companies should ensure these changes do not compromise the integrity, safety, and standard of their products, and that the new product is fully compliant with applicable product safety standards.

6.4 BE DILIGENT WITH RECORD MAKING & KEEPING

Companies should consider in advance their mechanisms for tracing and recording their consideration of ESG obligations to assist in establishing due diligence and complying with reporting requirements. Streamlined and formalized report forms should be made. Systems to flag growing concerns should also be implemented. Ideally, a separate and dedicated business unit should be created for compliance with ESG obligations. Such systems should ensure they capture all relevant information that is covered by the legal frameworks.

Check out our In Practice Series – How To Be An ESG-Conscious Product Manufacturer

7. Product Compliance Checklist

From our market research, speaking to our customers and many in the market, here is a checklist we put together for product compliance teams to follow through to drive an efficient compliance program,

Identify business objectives for each of your markets.

Identify the relevant regulations, standards, and internal policies for each product in each market.

Interpret the relevant regulations and standards to understand how they impact your products.

Determine the necessary evidence to prove compliance for each product in each market.

Determine the necessary resources for meeting compliance with relevant regulations and standards.

Recommend how to comply with relevant internal policies, regulations, and standards.

Gain agreement with decision-makers on the regulations and standards you will commit to.

Gain agreement from stakeholders on how each product will change to meet compliance requirements.

Communicate the relevant compliance requirements to the right department members who need to implement the requirements.

Ensure that the product's design covers relevant compliance requirements throughout the product lifecycle (from transportation to end of life).

Ensure that compliance is maintained during manufacturing.

Compile evidence of compliance for quick reporting.

Provide evidence of compliance to internal stakeholders.

Provide evidence of compliance to external stakeholders in each market.

Remediate product compliance issues.

8. The Role of Technology

8.3.1 PRODUCT COMPLIANCE SOFTWARE

Compliance teams can utilize product compliance software solutions to streamline processes, track regulatory changes, and manage documentation.

Benefits

- Improved quality and consistency of compliance processes and solutions
- Cost reduction
- Simplified compliance processes
- Ability to operate with speed & agility
- Accelerate product launches
- Reduce non-compliance risks
- Proactive Vs. Reactive compliance

8.3.2 AI & AUTOMATION

Teams can leverage artificial intelligence & automation for tasks like risk assessment, data analysis, and compliance monitoring.

Benefits

- Time savings
- Reduce labor-intensive tasks
- Catch compliance 'misses' beforehand

You might find our recent guide interesting, Building a Business Case for a Product Compliance Solution: A How-to-Guide

9. The Future of Product Compliance

- A constantly evolving process

9.1 EMERGING TECHNOLOGIES

Expect to see more use of blockchain, IoT, and AI in compliance management to enhance transparency and efficiency.

Check out Compliance & Risks' Product Compliance technology solutions.

9.2 GLOBALIZATION TRENDS

Global markets will continue to grow, necessitating a stronger focus on international harmonized product compliance efforts.

9.3 REGULATORY PREDICTIONS

With ESG concerns being in the limelight, anticipate more emphasis on sustainability, data security, and product safety in future regulations.

10. How can **Compliance & Risks** help?

Our market research has shown that product compliance teams in global organizations have 5 key jobs to be done,

1 **Identify relevant regulations & standards** for each product in each market

2 **Interpret regulations & standards** to understand how they impact their products

3 **Communicate compliance requirements** to the right department members to gain agreement on the compliance plan & implement the requirements

4 **Demonstrate compliance** to unlock market access

5 **Stay on top of upcoming regulatory changes** to mitigate non-compliance risks

All of these challenges point to protecting revenue & market access for products around the world. Our Product Compliance Solution helps compliance teams with insights into existing & proposed regulations, enabling for future-planning and strategizing for revenue growth

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10.1 COMPLIANCE & RISKS' PRODUCT COMPLIANCE SOLUTION

Built for modern compliance teams, Our Product Compliance Solution, powered by the C2P Platform, empowers compliance teams to accelerate the ability to unlock market access for all their products in international markets.

With our Product Compliance Solution, you can identify regulations, interpret and collaborate on compliance requirements for new and existing products with confidence. Ensure your compliance evidence is up to date with evidence expiry alerts live-linked back to regulations, standards, and requirements. See below Image 3, Product Compliance Solution by Compliance & Risks.

With access to the most comprehensive global database of regulatory insights for your entire product portfolio, have peace of mind that regulations are monitored by our team of subject matter experts so that you can be proactive about unlocking global market access for your products.

Trusted by 300+ industry leaders & with a track record of propelling compliance teams with a 'Zero Surprise' Compliance program, we help you shift gears & accelerate global product launches. Slash non-compliance risks & safeguard your brand's reputation.
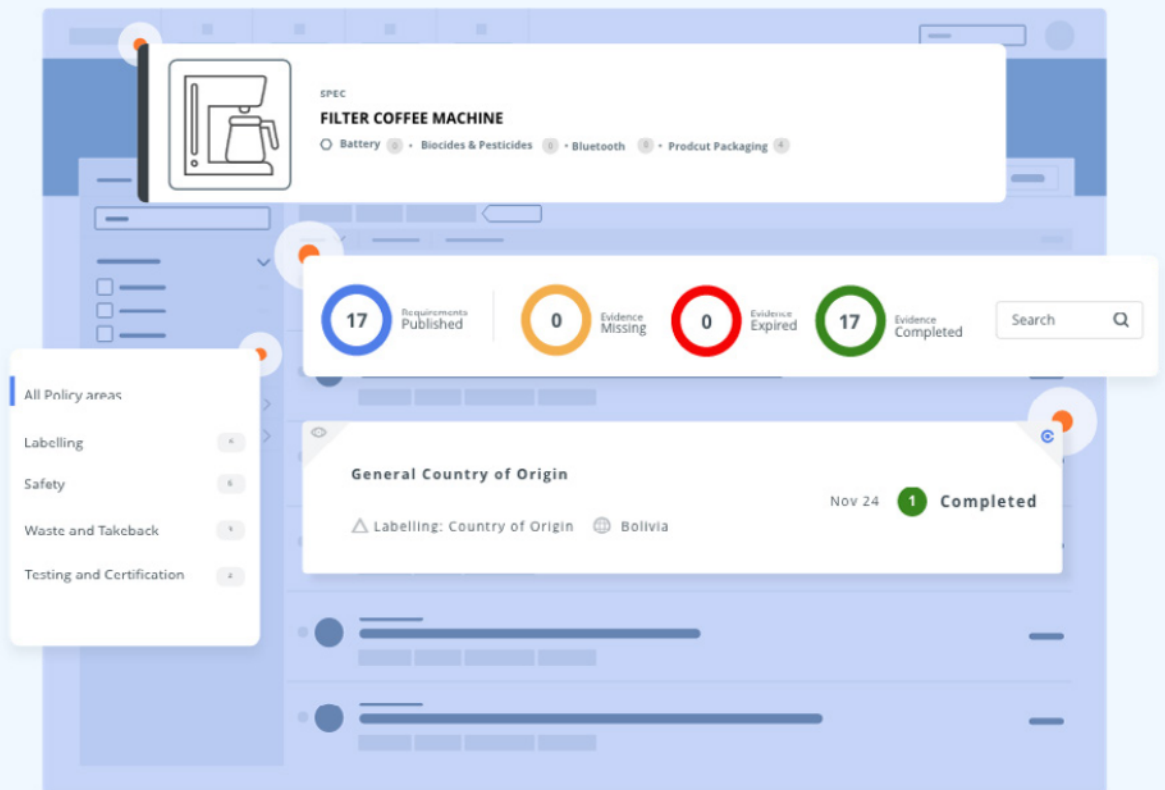
Image: Product Compliance Solution, powered by C2P Platform, Source: Compliance & Risks

10.2 BENEFITS

✓ **Accelerate Product Launches:** With a product portfolio view of your compliance efforts, effectively strategize and speed up time-to-market for your products.

✓ **Reduce Non-Compliance Risks:** Ensure 'Zero Surprises' with regular regulatory & compliance evidence expiry alerts, shielding business goals & brand reputation.

- ✅ **Proactive Vs. Reactive Compliance:** Shift gears on your compliance efficiency - say goodbye to last-minute firefighting to focus on strategic initiatives.

- ✅ **Save time** with access to Compliance & Risks' extensive Knowledge Partner network

- ✅ **Quickly align teams and stakeholders** around shared objectives.

- ✅ **Enable business continuity** by digitizing your compliance process & building corporate memory

- ✅ Continually **monitor regulatory changes & keep ahead of proposed changes** before they happen

- ✅ Integrate with other internal systems to enable **streamlined business processes**

INTERESTED IN LEARNING MORE?

Reach out to us to understand how we can better solve for your product compliance success.

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OUR NUMBERS

300+
CUSTOMERS WORDLWIDE

195
COUNTRIES COVERED

90,000
REGULATIONS

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