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Healthcare Industry

How ready are you for the CSDDD?

EU Due Diligence Legislation:

Impact on Procurement and Supply Chain Management & Steps to Compliance

Agenda

INVERTO analysis based on a holistic survey of 681 participants from companies with over 500 employees, operating in different industries, incl. healthcare

Study

- The results presented here are based on data collected by Verian
- Online survey of 21 questions conducted from **10/11/2023 to 03/12/2023**

Sample

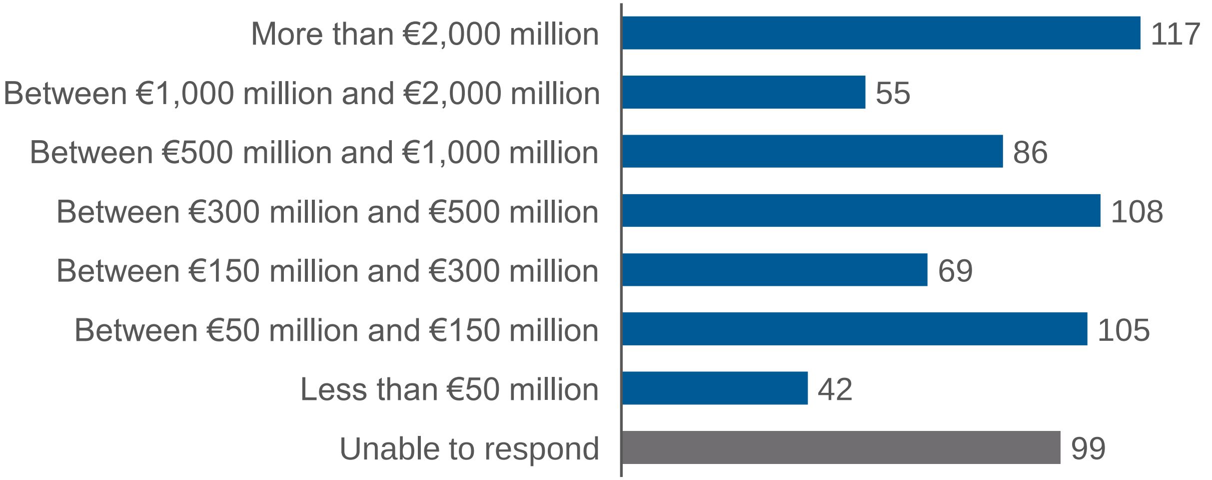
- Managing directors, board members, managers and other persons with procurement/supply chain responsibility in companies with more than 500 employees.
- **681 respondents**, including 351 from France and 330 from Germany
- Companies from 3 sectors:
  - Industry
  - Retail
  - Services
- **74 respondents from the healthcare industry incl. pharmaceuticals**

Data collection

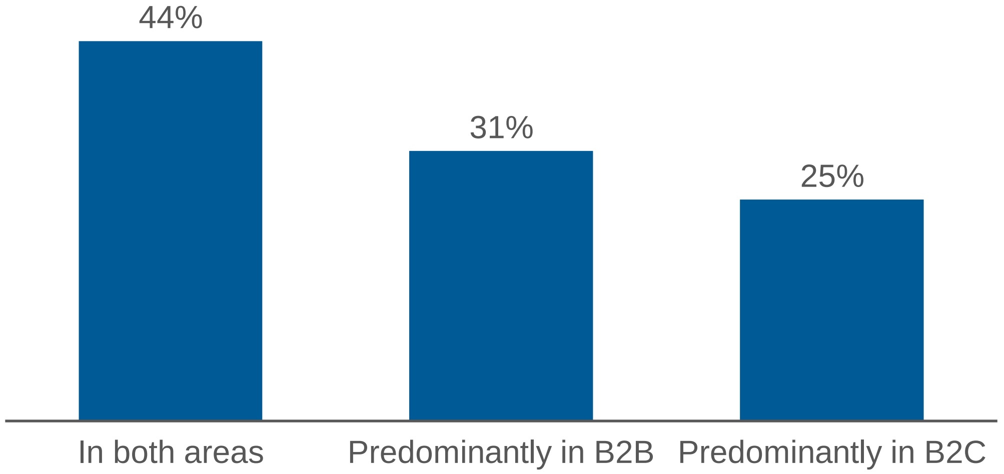
- Data was processed in 4 categories:
  - All respondents from France
  - All respondents from Germany
  - Procurement and SCM
    - CPOs
    - Procurement managers
    - Logistics managers
    - Other procurement functions
  - Executive committee member:
    - CEO
    - CFO
    - COO

Survey participants come from a diverse range of industries, with 11% working in the healthcare and pharmaceutical sector

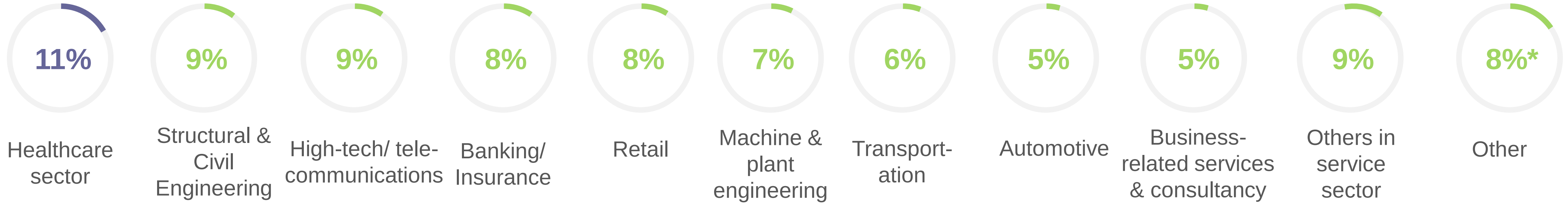
What was your company's annual turnover in 2022?



In which of these areas does your company operate?

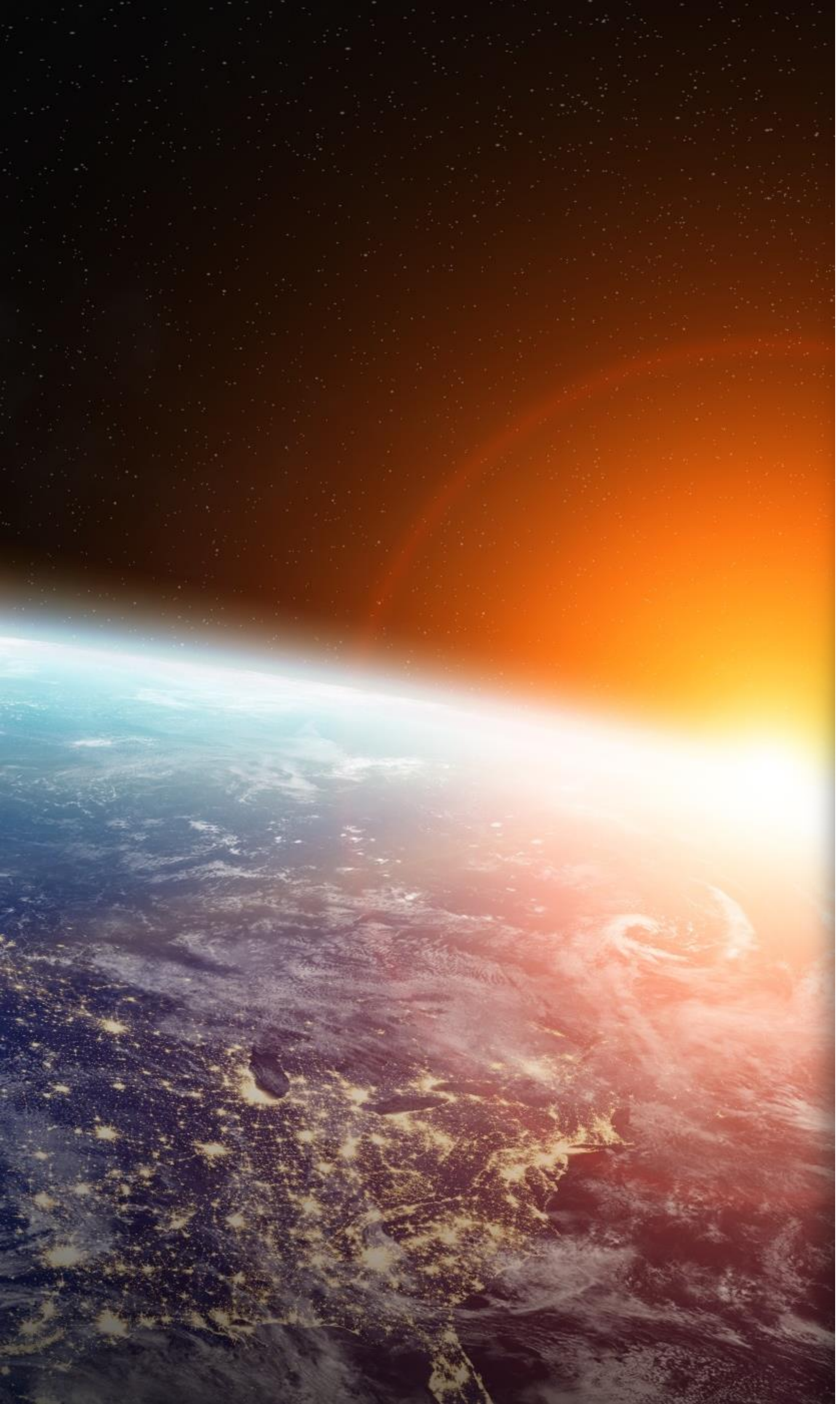


Which industry do you operate in?



*Consumer goods, Service for private individuals

Agenda



Due diligence as an obligation to promote human rights and environmental protection

- The European Corporate Sustainability Due Diligence Directive (CSDDD) complements the Corporate Sustainability Reporting Directive (CSRD) introduced in 2024
- The aim is to oblige companies to **monitor and minimize their negative impact on human rights and the environment**
- **The Directive enters into force on 25 July 2024** after its publication in the Official Journal of the European Union. Member States will have two years to transpose the Directive into national law and communicate the relevant texts to the Commission. One year later, the rules will start to apply to companies, with a gradual phase-in between 3 and 5 years after entry into force, i.e., July 2027 to July 2029

The European Corporate Sustainable Due Diligence Directive is the result of more than 10 years of reflection

2013

April 24, 2013
Rana Plaza collapse in Bangladesh with 1,100 fatalities

2017

March 27, 2017
French law concerning the due diligence obligations of holding companies and contracting companies

2019

November 13, 2019
The Netherlands passes a law banning the provision of goods and services by child labor

2021

June/July 2021
Norway passes a law on due diligence

2023

January 1, 2023
German due diligence law takes effect

June 1, 2023
The European Parliament votes in favor of the CSDDD[1]

December 14, 2023
The European Parliament, the EU Council and Commission reach an agreement on the directives

2024

January 1, 2024
Entry into force of the CSRD[2] adopted by the European Parliament in 2022

May 24, 2024
CSDDD approved by member states

July 25, 2024
Entry into force of the CSDDD after being published in the Official Journal of the European Union

Trigger — Relevant legislation

[1] CSDDD: Corporate Sustainability Due Diligence Directive
[2] CSRD: Corporate Sustainability Reporting Directive

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CSRD and CSDDD - two European directives to raise companies' awareness of their social responsibility

	CSRD: Commitment to transparency[1]	CSDDD: Due diligence (status July 2024)[2]
	CSRD establishes extra-financial reporting obligations to encourage corporate sustainability	The CSDDD establishes the legal responsibility of a company in cooperation with their direct suppliers, which includes the identification, prevention and mitigation of social and environmental impacts
Key data	Effective from: 01/01/2024 Vote: 2022	Effective from: 27/07/2026 - after 2 years time to transpose the Directive into national law. In-scope companies will be required to comply within a staggered timeline ranging from July 2027 to July 2029.
Companies	• Companies affected as of 01.01.2024: > 500 employees; turnover > € 40mn and € 20mn balance sheet total • Companies affected as of 01.01.2025: > 250 employees; turnover > € 40mn and € 20mn balance sheet total • Companies affected as of 01.01.2026: Listed SMEs except micro-enterprises	• *Three years after entry into force*: EU companies and parent companies > 5,000 employees; turnover (global or generated in the EU) > € 1.5bn • *Four years after entry into force*: EU companies and parent companies > 3,000 employees; turnover (global or generated in the EU) > € 900mn • *Five years after entry into force*: - EU companies and parent companies with > 1,000 employees; turnover (global or generated in the EU) > € 450mn - Franchise companies based in the EU with turnover > € 80mn if at least € 22.5mn generated through license fees (For non-European franchise companies, thresholds refer to turnover generated in the EU)
Parameters	Companies have to: • Provide detailed information on their environmental, social and, governance impacts • Publish reports on the risks and opportunities associated with these aspects • Use a standardized electronic reporting format	Companies have to: • Identify and manage impacts on human rights and the environment, including prevention, mitigation of potential risks and remediation of existing impacts • Establish grievance mechanisms, monitor the effectiveness of the measures and report transparently

[1] Source: https://finance.ec.europa.eu/capital-markets-union-and-financial-markets/company-reporting-and-auditing/company-reporting/corporate-sustainability-reporting_en#legislation
[2] Source: https://eur-lex.europa.eu/

The directives require companies to introduce preventive and corrective measures to avoid possible sanctions

Companies are expected to take measures to fulfill their due diligence obligations

- **Incorporating** due diligence into corporate guidelines
- **Identification** of actual or potential negative impacts of its own activities and those of its subsidiaries on human rights and the environment
- **Avoiding or mitigating** potential impacts and stopping (or minimizing) actual impacts with action plans tailored to the company's activities, contract amendments, project-, investment- or management adjustments
- **Establishing and maintaining** a procedure for complaints and internal warnings
- **Ongoing review** of the effectiveness of security guidelines and measures
- **Public communication** about the Due Diligence Directive

Monitoring measures and sanctions in accordance with the CSDDD[1]

Each state is required to set up a national supervisory authority to monitor and investigate companies' compliance with the regulations, and to sanction companies.

Inspections and investigations

In the future, companies will be held accountable for damages caused by CSDDD violations

Fines of up to 5% of a company’s global net turnover

[1] Source: https://eur-lex.europa.eu/

The European CSDDD guidelines go beyond the guidelines of national regulations

Current regulations (Germany)

1. Companies based in Germany as of 2023:
   - Number of employees > 3,000
2. Companies based in Germany as of 2024:
   - Number of employees > 1,000

Current regulations (France)

1. Companies based in France:
   - Number of employees > 5,000
2. Foreign companies based in France:
   - Number of employees > 10,000

New regulation (gradual phase-in from July 2027 – 2029)

- *Three years after entry into force*: EU companies and parent companies > 5,000 employees; turnover (global or generated in the EU) > € 1.5bn
- *Four years after entry into force*: EU companies and parent companies > 3,000 employees; turnover (global or generated in the EU) > € 900mn
- Five years after entry into force (from July 2029):
  - Companies in the EU and third-country companies operating in the European Union: > 1,000 employees; turnover > € 450mn
  - Franchise companies based in the EU; turnover > € 80mn if at least € 22.5mn generated through license fees
- Note: Temporary exclusion of the Financial sector from the scope of the Directive

Current parameters (Germany)

- The companies' due diligence measures cover **the entire supply chain** - from raw materials to the final sales product
- The requirements are graded according to the company's size

Current parameters (France)

Identify, assess, mitigate, alert and monitor risks within:
- Subsidiaries
- Subcontractors
- Suppliers

New parameters: the activity chain

Identify, assess, prevent, mitigate, end, and remedy the negative impacts of its activities on people and the planet and on its partners, in particular with regard to:

- Production
- Procurement
- Transportation
- Warehousing
- Planning
- Distribution

The activity chain comprises the activities of the upstream and parts of the downstream value chain. In the downstream value chain, transportation, storage and distribution are only considered in direct business relationships, whereas the disposal of products is completely exempt from audits.

Agenda

Healthcare (HC) companies are receptive to more stringent regulations, despite difficulties related to a lack of transparency and understanding

HC companies prioritize financial performance of procurement (priority 1) well ahead of ESG aspects (priority 8)
This is due to the successive Covid crises, the war in Ukraine, and other geopolitical and economic crises that have impacted prices and supply capacities. As the study shows, the main challenges faced by healthcare companies over the past 3 years have been resolving shortages of manpower (65%), supply bottlenecks (50%), shortages in raw materials (47%) and a lack of alternative suppliers (44%).

26% (DE) vs. 10% (FR) of HC employees express a very good level of understanding of their national due diligence directive. Compared to the industry average, HC employees feel less informed and less prepared for EU regulatory changes
This is what we are seeing with our clients, where the principles of the directive are struggling to be translated into planned, structured initiatives. 46% of staff in the healthcare sector do not feel well trained regarding regulatory changes and developments related to due diligence. Until now, too few companies have drawn up a double materiality matrix, the key to appropriating the law's concepts.

For HC companies, it is the regulation that is driving them to act (motivation 1), even before corporate social responsibility (motivation 2) or consumer perception (motivation 3)
Actions taken include monitoring KPIs, developing compliance policies, and introducing supplier selection criteria. Nevertheless, for 32% of employees in procurement and supply chain functions, these actions come up against a lack of transparency in their supply chain, explaining the need for external support to build an implementation strategy on both business and data management aspects.

In the long term, 84% of HC companies expect a positive impact of the regulation regarding social and environmental responsibility, while 16% fear a loss of competitiveness
This is due to the importance of procurement costs, the weight of purchasing in their sales, and the pressure of the new directive on suppliers who will have to finance this transition. Nevertheless, companies are realistic about the need to invest in the short term to make this transformation a success.

Companies see a need to upgrade skills through training, recruitment, and external expertise
Only 16% of respondents in the HC industry report a need for monitoring tools, even though these are key to the transformation. Procurement and supply chain managers can act upstream and actively deploy supplier data monitoring to guarantee their ability to meet CSDDD criteria.

Agenda

1 Study Design and Participants

2 The Corporate Sustainability Due Diligence Directive (CSDDD)

3 Management Summary

4 Survey Results: Healthcare (HC) vs. all industries

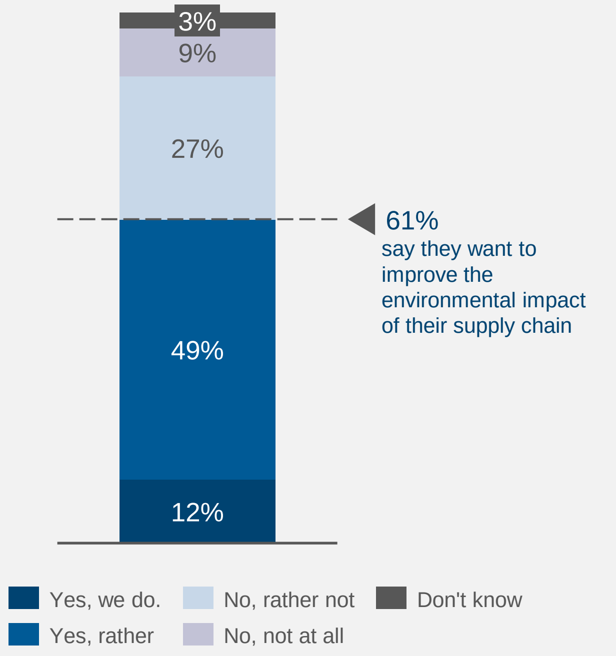
- Business priorities
- Knowledge of legislation
- Compliance actions and measurements
- CSDDD Impact
- Support & General opinion

5 Recommendations for Action

While 61% of HC respondents want to improve the social and environmental impact of their supply chain, only 18% include it in their top 3 priorities

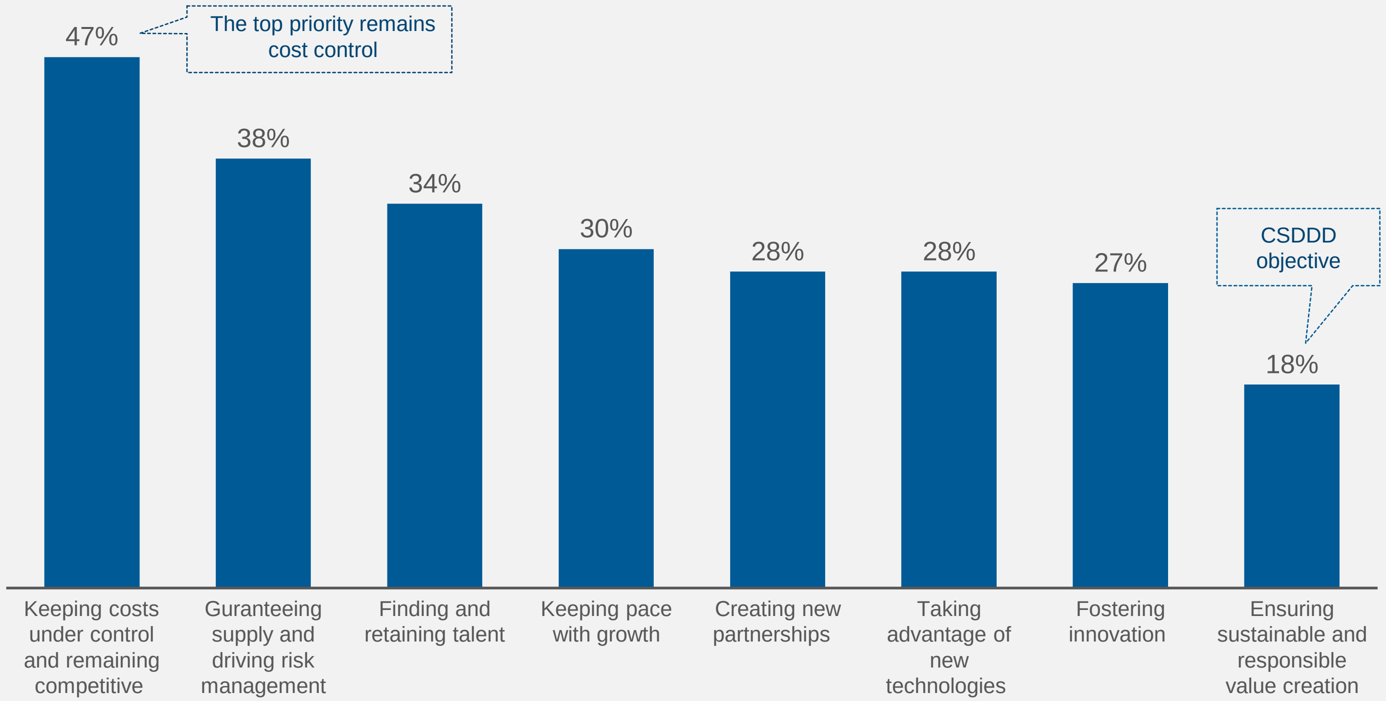
Topic awareness

Do you currently feel that optimizing the supply chain in terms of environmental protection and human rights is a priority for your company?



Priorities

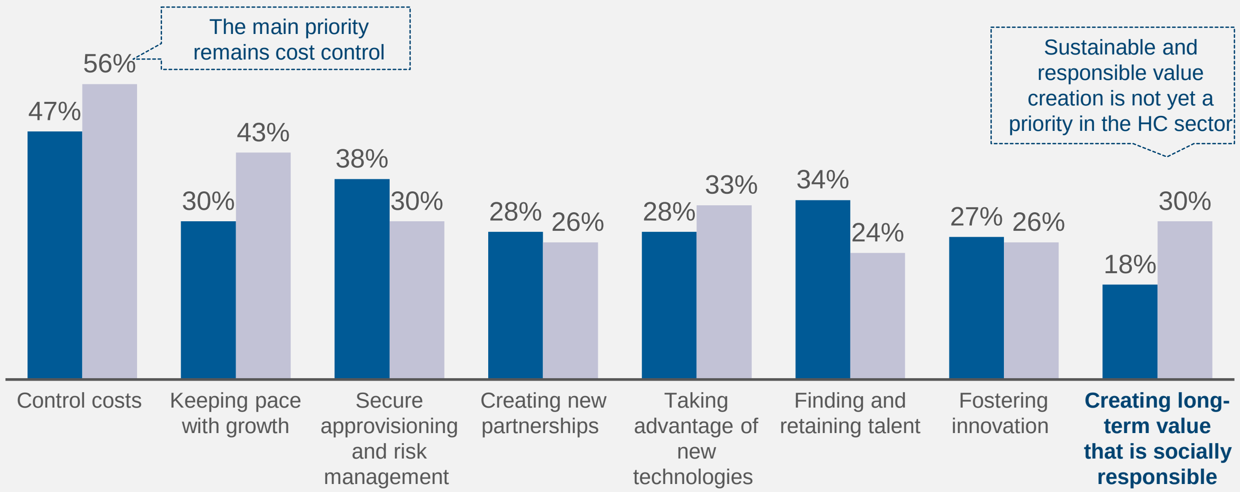
In terms of procurement, what are the top 3 priorities for your company? (multiple answers: max. 3)



In the healthcare sector, social responsibility is a relatively low priority; awareness of national legislation is given, yet German HC companies are more familiar

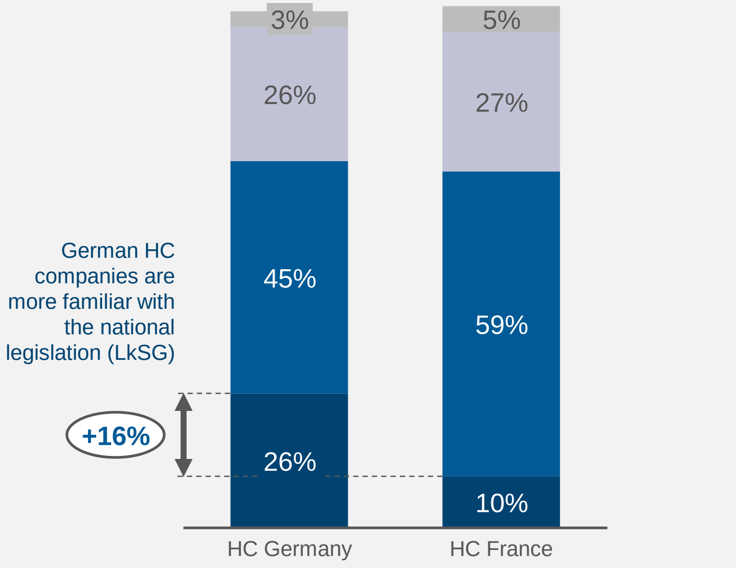
Priority ranking (HC / Pharma vs. other sectors)

What are the **top three procurement priorities** your company is facing? (max. 3 choices)



Awareness of national regulations

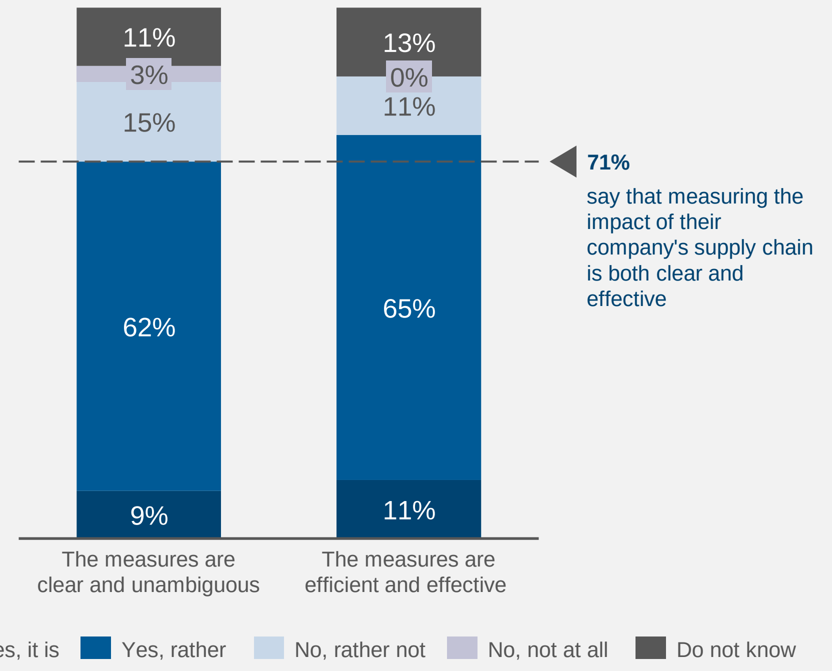
At your level, are you familiar with the **national legislation** already in place on duty of care?



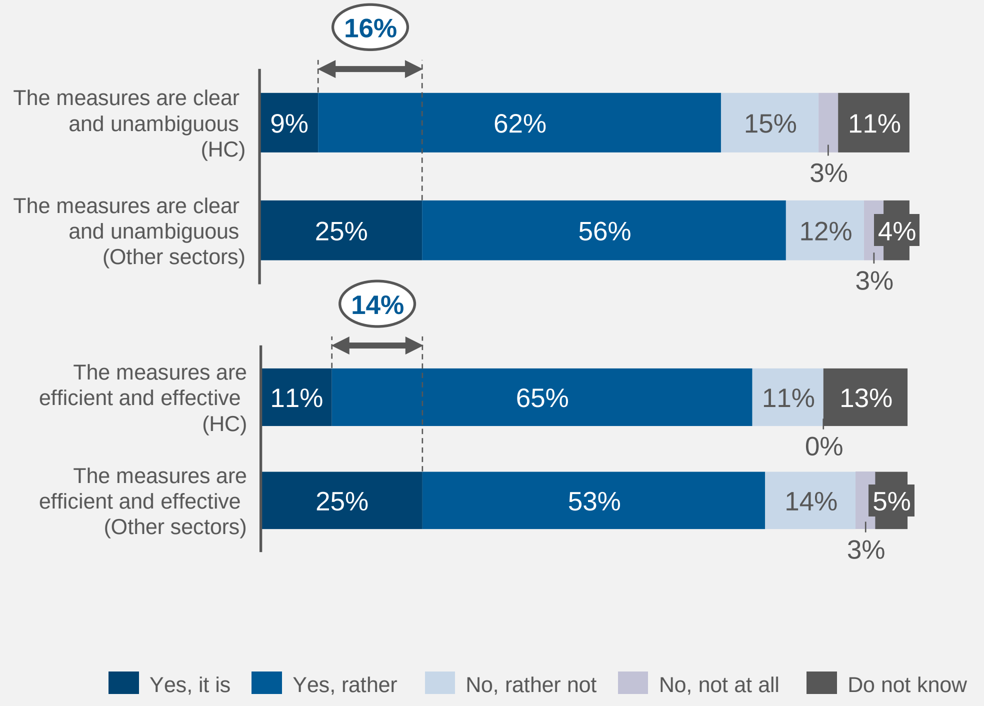
While there is a predominantly positive view across sectors on the management and measurement of supply chain impacts, HC's perception falls below average

HC: Perception of internal policy for managing and measuring supply chain impacts

What do you think of your company's policy for managing and measuring supply chain impacts?



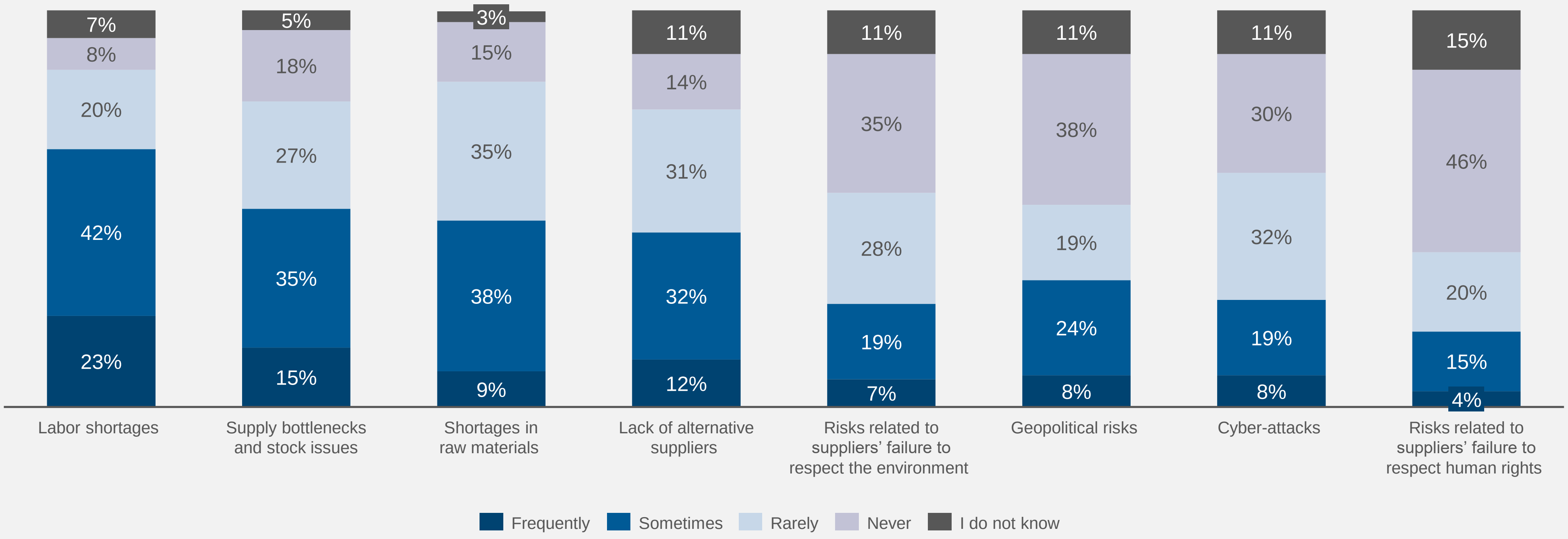
HC vs. other sectors



Over the past 3 years, HC supply chains have been weakened mainly by shortages of labor, supply bottlenecks and lack of alternative suppliers

Major supply chain weaknesses in healthcare

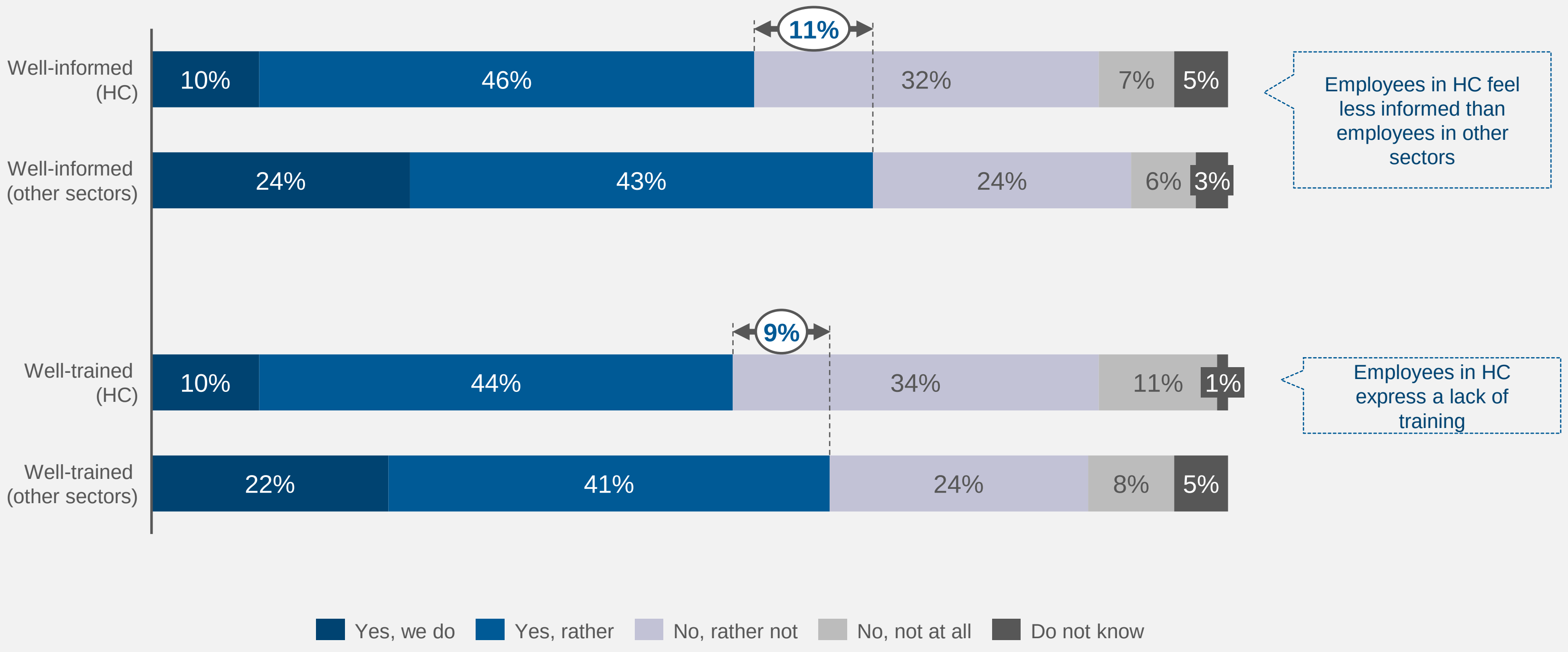
Over the past 3 years, has your supply chain been affected by the following risks and challenges?



Employees in HC feel less informed and trained when it comes to the planned EU due diligence regulations

Information on EU regulatory developments

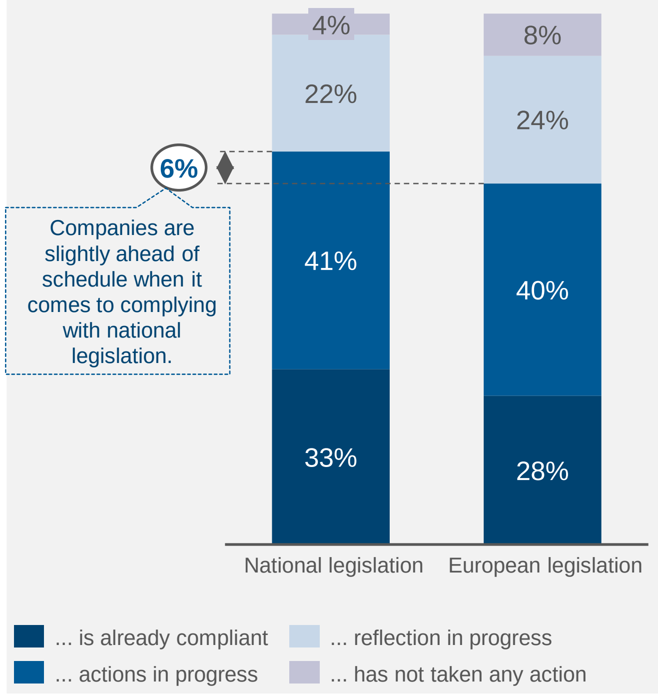
When it comes to the planned EU due diligence regulations, would you say that you are…



Around three quarters of the companies are either in compliance or in the process of becoming compliant with both European and national regulations

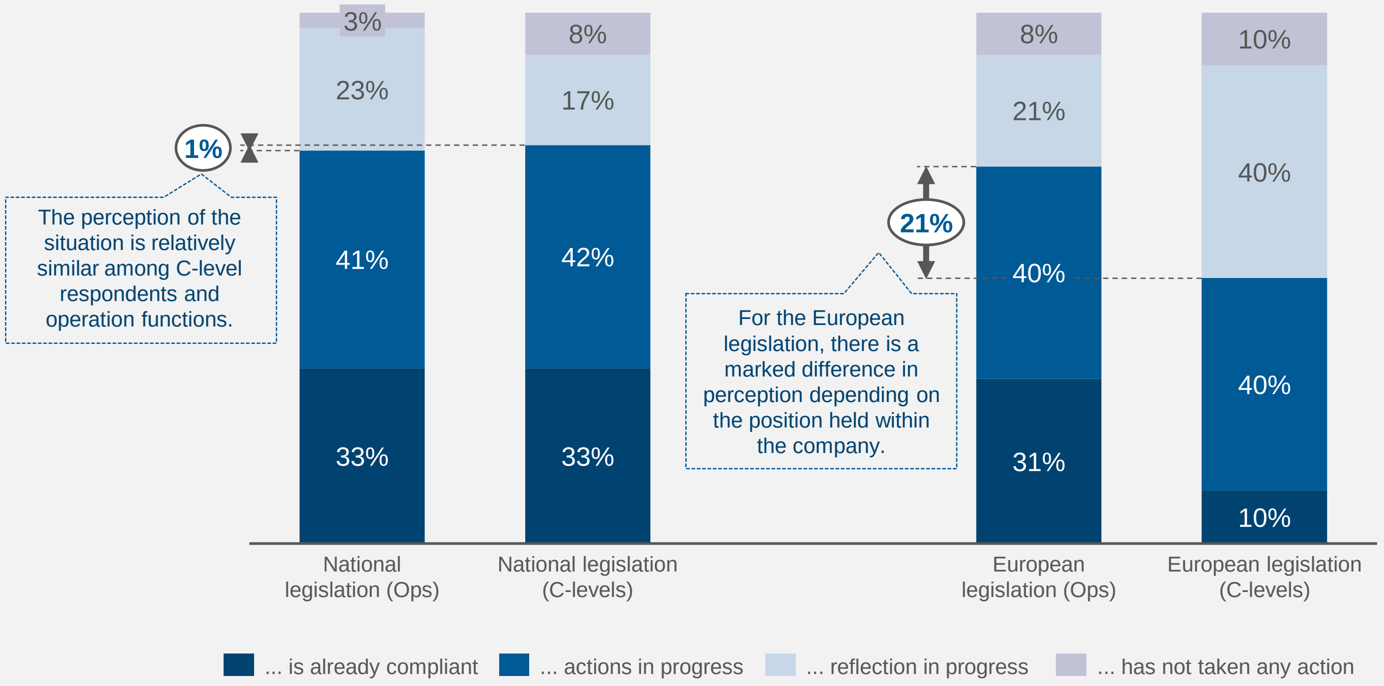
Perception of companies' preparation for regulations

Which statement do you feel most appropriately describes your company's current level of compliance?



Perception of preparation depending on position

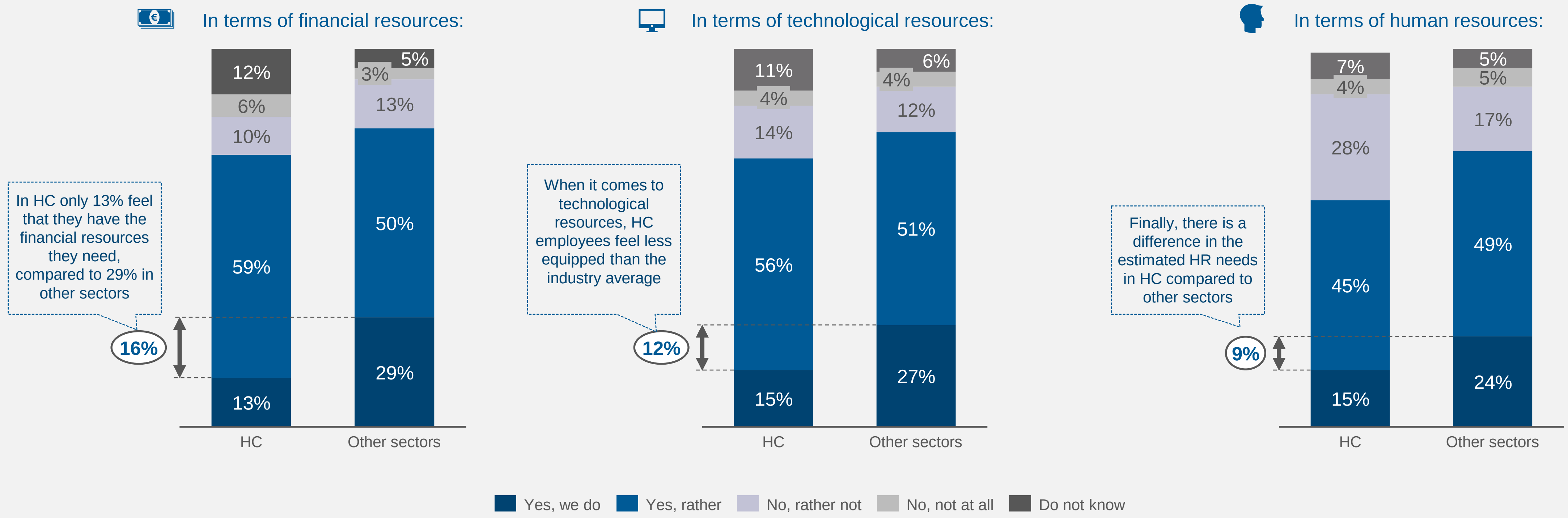
Which statement do you feel most appropriately describes your company's current level of compliance?



Even though most companies believe that they have the necessary resources to ensure compliance with the EU regulations, the HC sector is less optimistic

Evaluation of internal resources for compliance

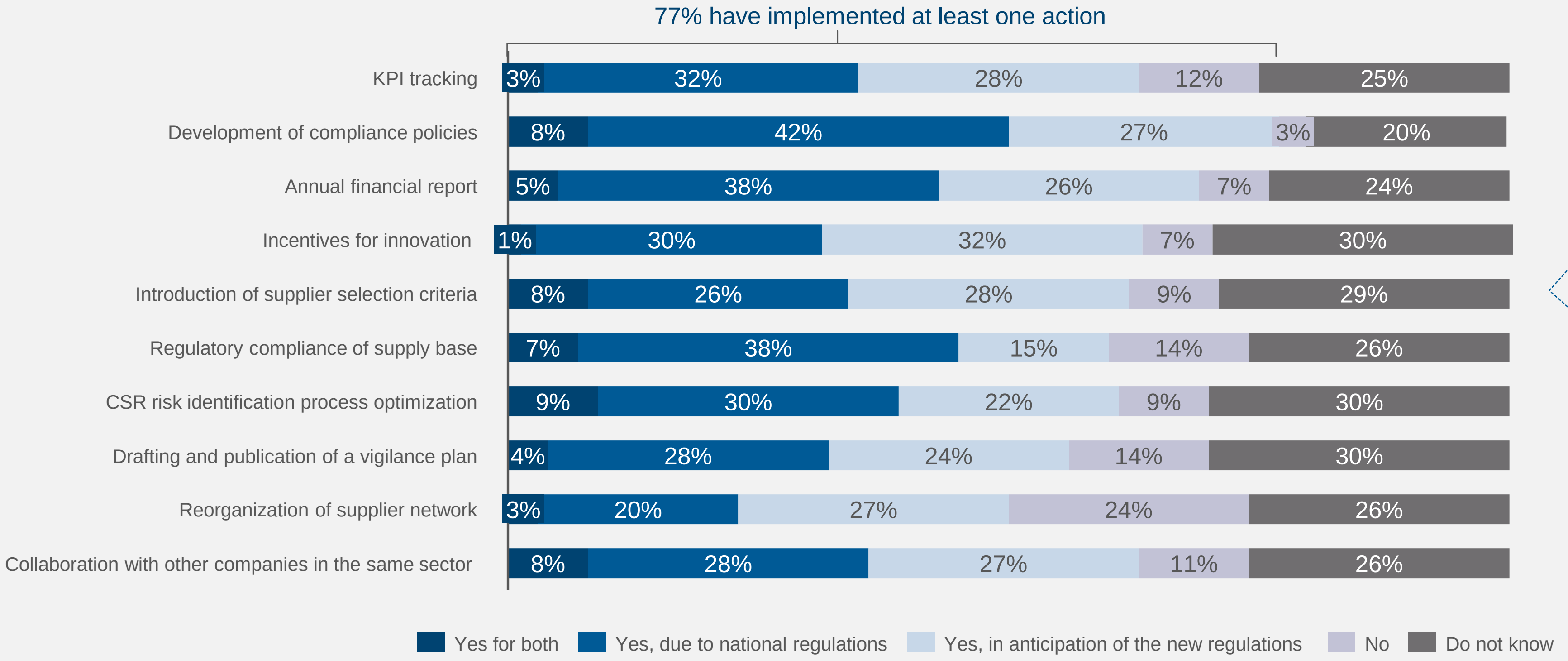
Does your company have the necessary resources to ensure professional supply chain management in compliance with the new EU regulations... ?



Numerous measures are already in place or planned to comply with national and European legislation, but these initiatives suffer from a lack of internal visibility

Compliance actions

Which of the following measures has your company considered or already taken to achieve compliance at national or European level?

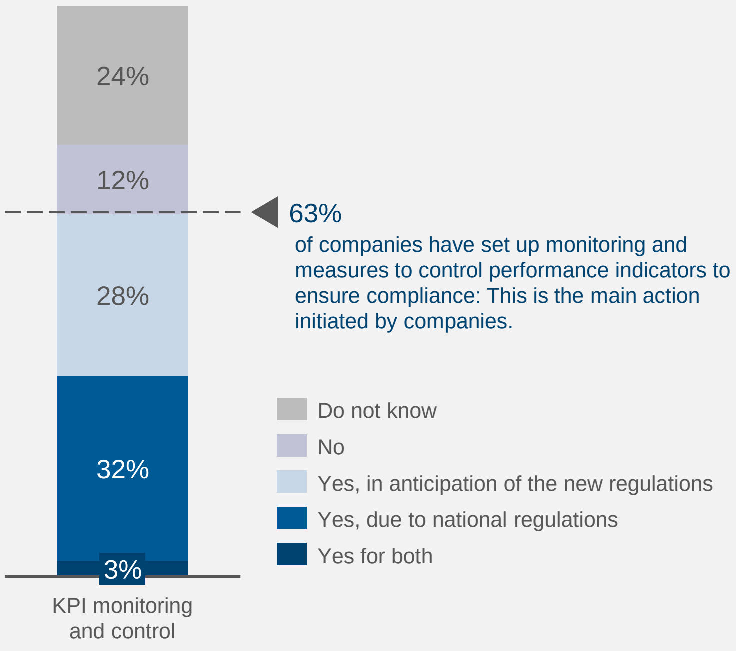


The proportion of respondents who don't know whether the following actions have been implemented reflects a **lack of visibility and internal communication**.

Complying with legal obligations and monitoring CSR issues are the main motivators for HC companies to achieve compliance

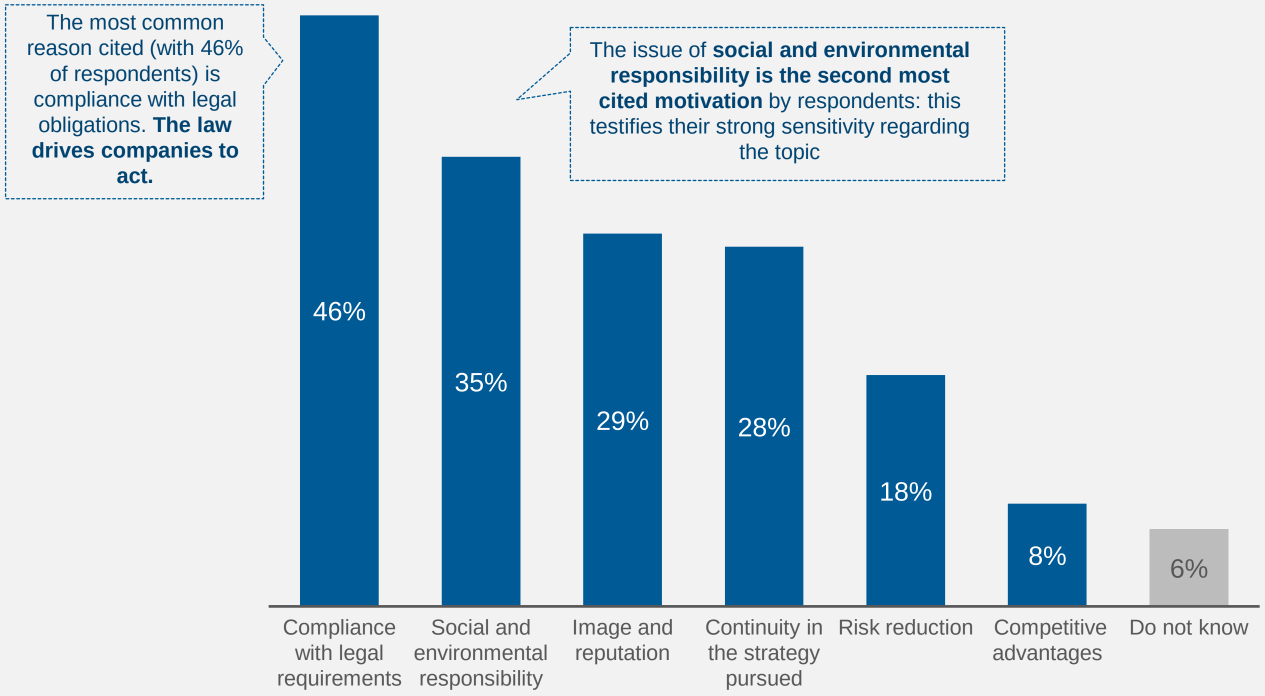
Example of implemented actions

Companies who have implemented KPI monitoring and control measures to comply at national or European level



Reasons for driving the measures forward

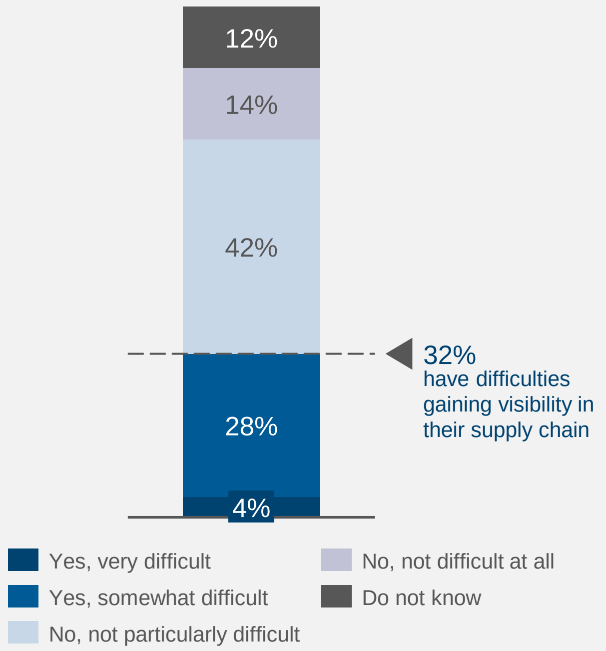
What is the main rationale behind these measures? (2 answers max)



A lack of capacity, strategy, and comprehension of the regulation is holding back companies' compliance efforts

Stakeholder transparency

Do your procurement and SCM functions find it difficult to get a complete, transparent overview of the supply chain, particularly in terms of whether suppliers respect human rights and comply with environmental protection regulations?

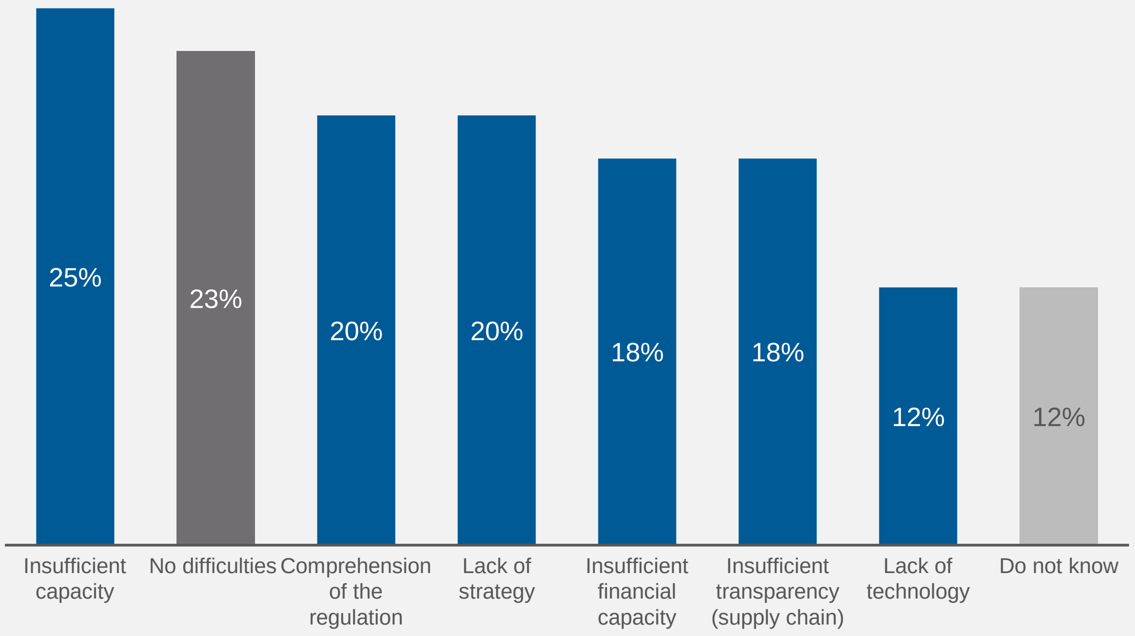


Barriers to concrete action

Which are the most common challenges facing your company when it comes to implementing the measures? (multiple answers)

The main obstacles to concrete action are a **lack of capacity and a heterogeneous understanding** of the directive.

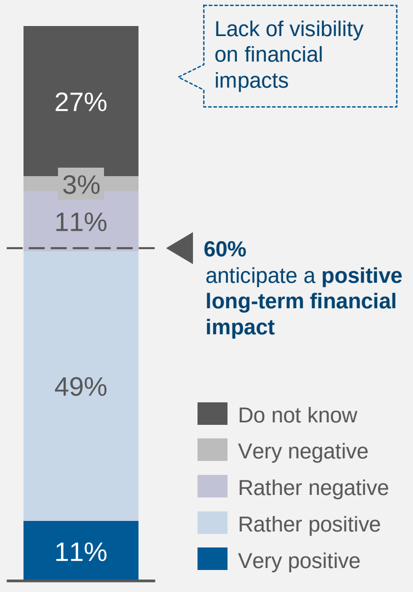
As a result, companies find it **hard to identify the levers to create an impactful strategy**.



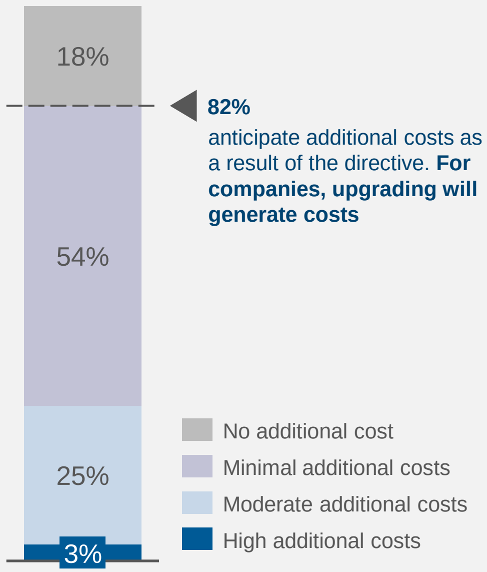
Despite the additional costs and potential competitive disadvantages, the new regulations are seen as an opportunity to leverage long-term positive impact

Anticipated financial impact

What financial impact do you expect in the long term? (in relation to ROI)

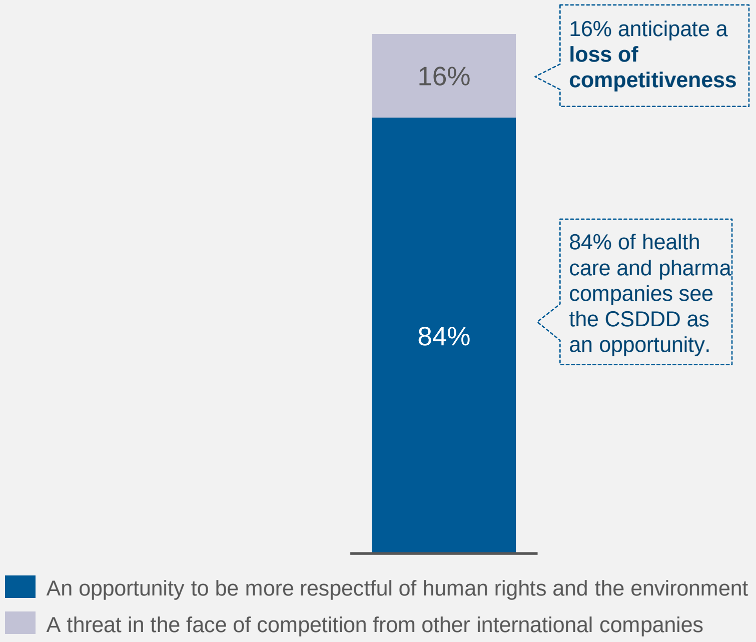


How do you feel compliance with the new EU directive will impact your company in terms of costs?



Impact perception

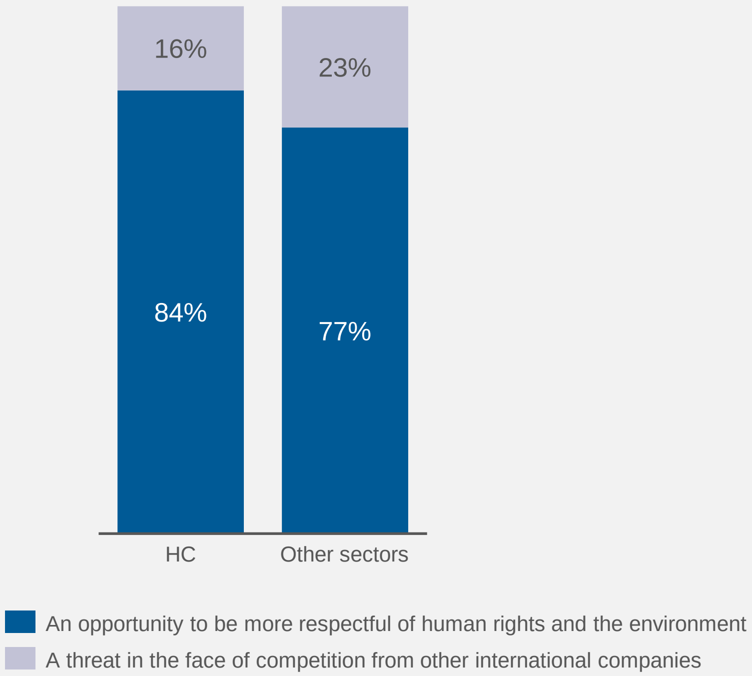
How do you see the new regulations for your company?



HC are more optimistic regarding the CSDDD - for large HC companies, compliance is only associated with slightly higher costs

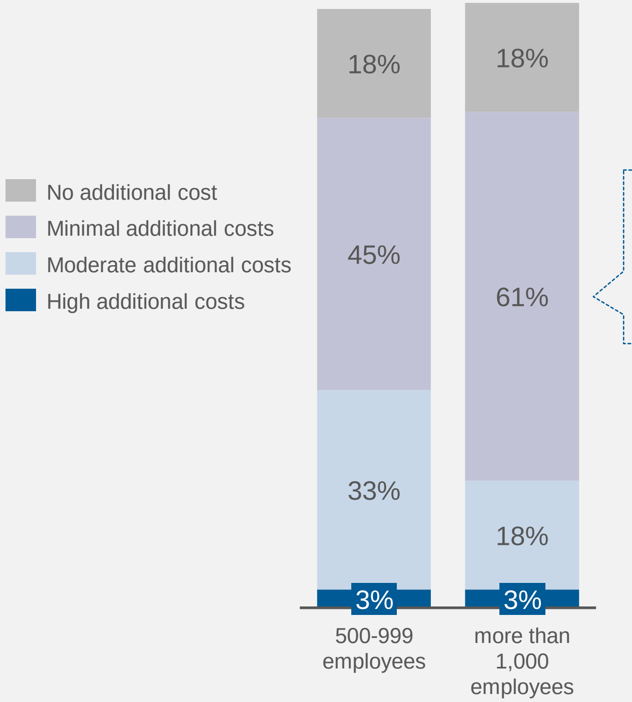
Focus on sector

How do you see the new regulations for your company?



Focus on company size in HC

How do you feel compliance with the new EU directive will impact your company in terms of costs?

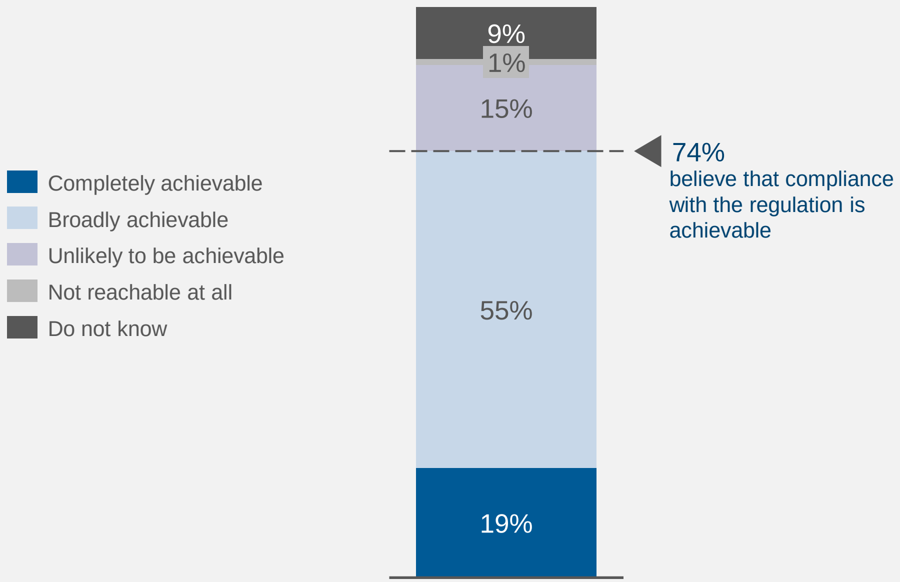


There are additional costs for both large and small companies. However, the costs are lower for large companies.

74% of HC companies are confident that compliance is achievable for their business - doubts exist among companies with a turnover higher than € 500 mn

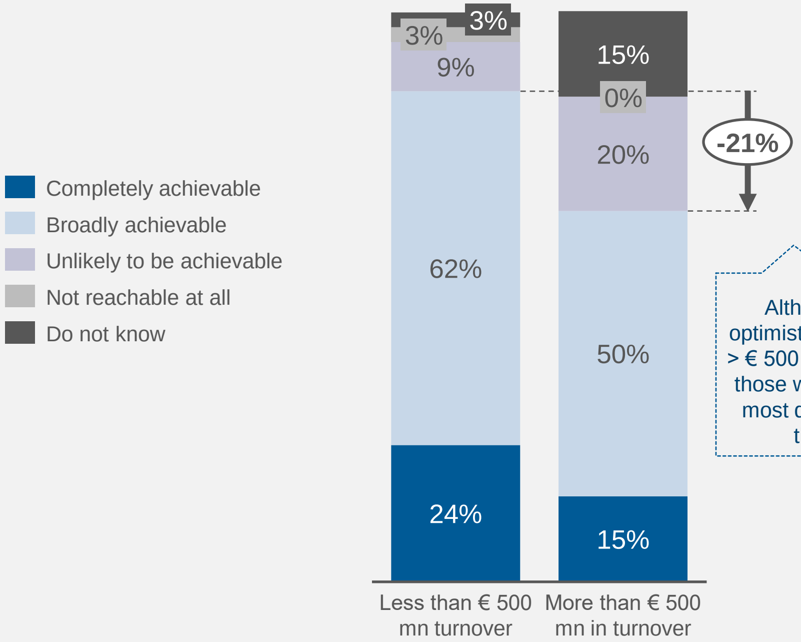
Implementing the directive

In your opinion, complying with the due diligence regulations is a goal that is…



Focus: Turnover

In your opinion, complying with the due diligence regulations is a goal that is…

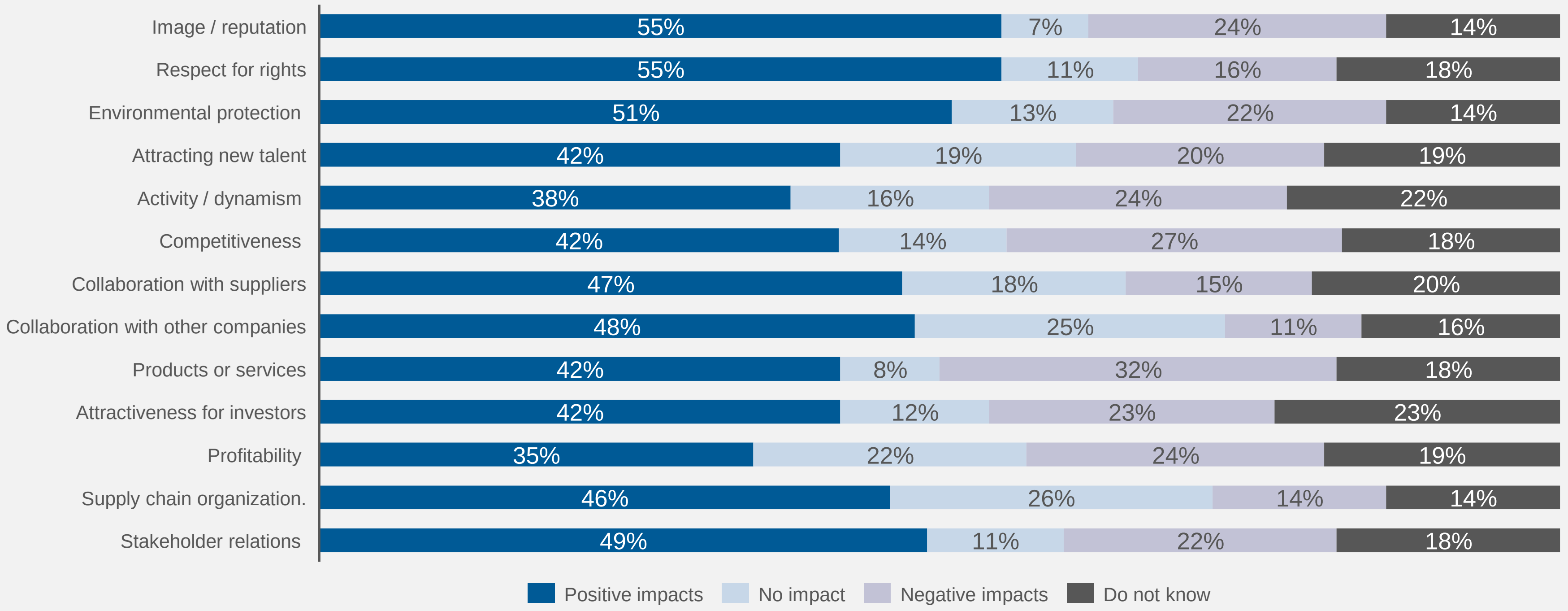


Although generally optimistic, companies with > € 500 mn in turnover are those who consider it the most difficult to achieve their targets.

Overall, HC companies anticipate a fairly positive impact from regulations, particularly on their image and attractiveness for new talent

Anticipated impact on the company

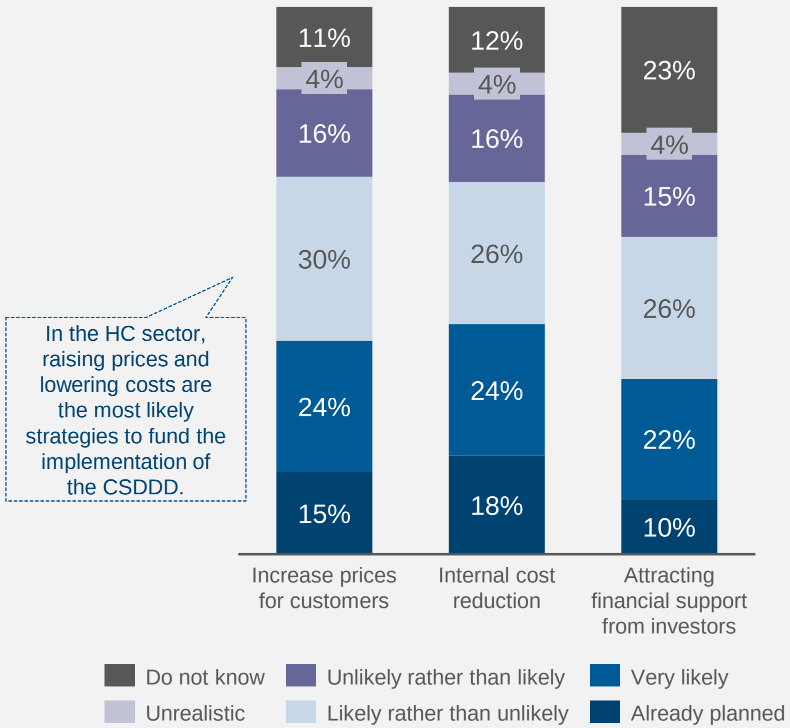
Do you believe that introducing more stringent due diligence into the supply chain will have a positive, negative or no impact at all on the following?



In HC, raising prices and reducing costs are the most viable way to finance CSDDD compliance, while trainings aid in the adoption process

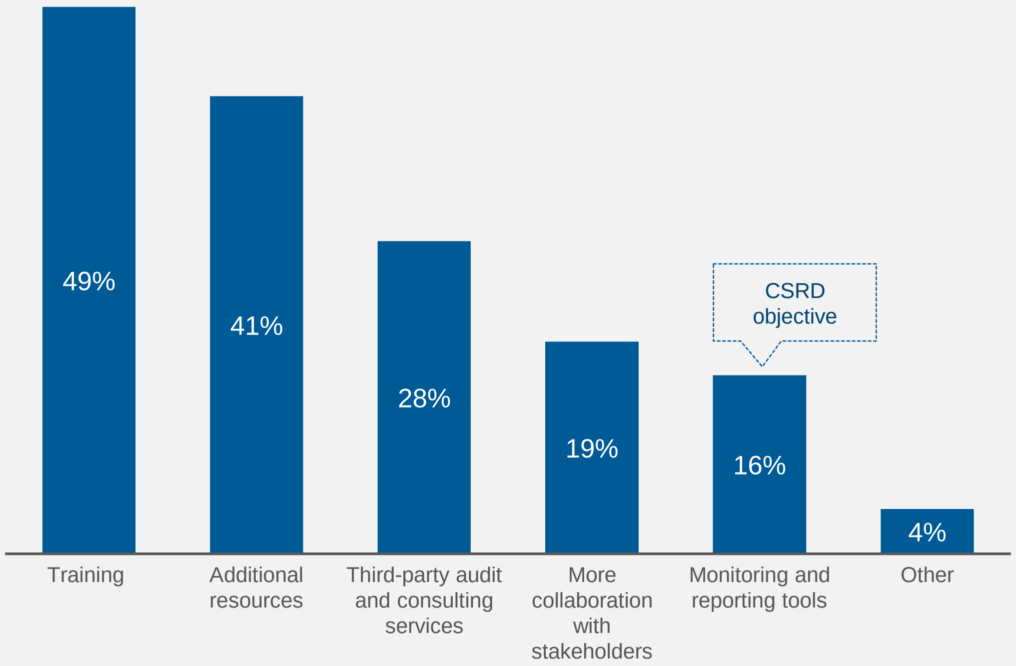
Financing measures to ensure compliance with regulations

Do you believe the following levers can be used to finance and support the implementation of and compliance with the new regulations in your company?



Needed support

What form of support do your procurement and supply chain management in particular require to overcome the challenges posed by the new EU rules and regulations?



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Recommendations for Action

The CSDDD is a door opener to gain visibility and control over the entire supply chain, provided strategic measures are taken

Setting up a performance plan

To successfully adapt to the new CSDDD measures, it is essential for companies to proactively develop a cross-functional performance plan that effectively combines cost control, CSR commitment and increased resilience.

Proactive procurement initiatives

To ensure that they are not penalized by the new measures, procurement departments must act independently and proactively, taking the initiative with their senior management. This involves updating procurement data, gaining a deeper understanding of the supply chain, and drawing up a dual materiality matrix*.

*An explanation of the principle can be found here: [Double materiality: Broadening corporate sustainability reporting to encompass societal and environmental impacts | Cambridge Institute for Sustainability Leadership (CISL)]

Recommendations for Action

Enhance ESG integration

In anticipation of the CSDDD, HC companies need to prioritize the integration of ESG criteria into their supply chain management. They must establish clear ESG performance indicators and engage suppliers in sustainability efforts to better align with CSDDD objectives and sector aspirations for sustainable supply chains.

Strengthen supply chain resilience and compliance

Given the sector's exposure to supply chain risks, healthcare companies must develop a strategic framework for resilience that includes diversifying supplier bases, implementing rigorous risk assessment processes, and enhancing cybersecurity measures.

Creating transparency and accountability

Through transparency, companies can identify cost-saving opportunities, enabling the strategic reallocation of resources. This does not only contribute to operational efficiency but further fosters compliance.

*An explanation of the principle can be found here: [Double materiality: Broadening corporate sustainability reporting to encompass societal and environmental impacts | Cambridge Institute for Sustainability Leadership (CISL)]

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See the overall, cross-industry survey results, here
www.inverto.com/CSDDD