

Non-Financial Statement**

The combined management report of Merck KGaA and the Merck Group for the fiscal year 2022 includes a combined non-financial statement in accordance with sections 315b and 315c in conjunction with 289b to 289e of the German Commercial Code (HGB) in the form of a separate chapter. Our non-financial statement orients towards the requirements of the Global Reporting Initiative (GRI) standards. It also includes our reporting in accordance with the EU taxonomy regulation.

KPMG AG Wirtschaftsprüfungsgesellschaft conducted a [limited assurance engagement](#) of the combined non-financial statement. References to information not included in the management report are not part of the non-financial statement. The additional content provided on both the company's websites as well as external websites that are linked in this report are not part of the information assured by KPMG – excluding references to our Sustainability Report. Our Sustainability Report 2022 is produced in accordance with GRI Standards. It will be available [online](#) as of April 13, 2023. With this, we also disclose topics set forth by Sustainability Accounting Standards Board (SASB) and Task Force on Climate-related Financial Disclosures (TCFD).

Description of our business model

Our business model as well as our Group structure, governance and strategy are described under "[Fundamental Information about the Group](#)".

Governance

The requirements we place on responsible corporate governance are derived from our [company values](#) on the one hand and from the regulations, external initiatives, and international guidelines to which we are committed on the other hand. We have integrated these requirements into our [sustainability strategy](#) and our [Group-wide guidelines](#). These guidelines comprise charters and principles that are valid for the entire company as well as specific standards and procedures for individual business sectors and sites.

Some examples: Our [Human Rights Charter](#) aligns with the [UN Guiding Principles](#) for Business and Human Rights. Our Group-wide [Social and Labor Standards Policy](#) reflects the labor standards of the International Labour Organization ([ILO](#)). Our [EHS Policy](#) (Corporate Environment, Health and Safety Policy) for environmental impact mitigation and health and safety forms the basis for implementing the chemical industry's [Responsible Care® Global Charter](#) within our company. Our standard entitled Corporate Chemicals Regulations Governance describes the processes and management structures required to ensure global compliance with the pertinent chemical and product safety regulations.

We comply with all applicable laws as a matter of principle. Where necessary, we review our internal guidelines, standards and instruction manuals on compliant behavior and adapt them to reflect changes in the regulatory landscape.

Roles and responsibilities

Based on the requirements set forth in charters, principles and policies, our internal standards give specific guidance for operational processes. They are constantly updated by the relevant departments and are available on our intranet. Our managers implement these standards in their respective areas of responsibility and ensure that they are adhered to. In addition, we educate and train our employees on all guidelines that apply to them.

We employ management systems to steer processes and define goals, actions, and responsibilities. These systems are based on standards such as the internationally recognized quality management standard ISO 9001, good working practices (GxP) in the pharmaceutical industry and ISO 14001 for environmental

** The summarized non-financial statement was not part of the audit of the financial statements but was subject to a separate limited assurance audit by KPMG.

management. Our company regularly undergoes [ISO 14001](#) and [ISO 9001](#) certification, which are conducted by an independent auditing firm. We hold group certificates for both standards.

We support the following responsible governance initiatives:

- United Nations [Global Compact](#)
- Chemical industry's [Responsible Care® Global Charter](#)
- Company network Together for Sustainability ([TfS](#))
- Pharmaceutical Supply Chain Initiative ([PSCI](#))
- Initiative Chemie³, a collaboration between the German Chemical Industry Association (VCI), the German Employers' Federation of the Chemical Industry (BAVC), and the German Mining, Chemical and Energy Industrial Union (IG BCE).

Strategic and organizational approach to sustainability

The world is facing multiple challenges that we too as a company face. These include climate change, international conflicts and economic crises, for instance. Our ambition is to leverage science and technology to achieve sustainable progress for mankind.

We describe our sustainability strategy in the "[Strategy](#)" section of the management report within the Annual Report for 2022 and, in more detail, in the Sustainability Report for 2022 in the chapter entitled "[Sustainability Strategy](#)".

Measuring progress made with the sustainability strategy

On the basis of 14 key indicators, which we defined back in 2021, we record and assess our progress towards achieving our sustainability goals. In 2022, we implemented various digital working tools that we believe will allow us gain greater transparency with regard to our achievements. Moreover, we added a sustainability factor to the Merck Long-Term Incentive Plan (LTIP) in 2022. It measures the performance of three selected sustainability goals over a period of three years, thus making it possible to increase or reduce target achievement resulting from the key financial performance indicators by up to 20%. Details on how this sustainability factor is calculated can be found in the [Compensation report](#).

Goal 1: In 2030, we will achieve human progress for more than one billion people through sustainable science and technology.

Focus area	Sustainability key indicator	Further details
Sustainability innovation and technology	Percentage of newly published patent families with positive sustainability impact	Sustainable innovation & technologies
Health and wellbeing impact	People treated with our Healthcare products¹	Will be published in the SASB index as of April 13, 2023

Goal 2: By 2030, we will integrate sustainability into all our value chains.

Focus area	Sustainability key indicator	Further details
Sustainability culture and values	- Percentage of women in leadership positions - Percentage of employees trained on sustainability	Diversity, equity and inclusion Attracting and retaining talent
Sustainable and transparent supply chain	Percentage of relevant suppliers (in terms of number and supplier spend) that are covered by a valid sustainability assessment¹	Responsible supply chain
Securing our social license to operate in all regions	- Environment, Health and Safety (EHS) Incident Rate - Violations of Global Social and Labor Standards Policy - Lost Time Injury Rate (LTIR)	Process, plant and transport safety Human rights Health and safety

¹The key indicator is used to determine the sustainability factor for the Merck Long-Term Incentive Plan (LTIP).

Goal 3: By 2040, we will achieve climate neutrality and reduce our resource consumption.

Focus area	Sustainability key indicator	Further details
Climate change and emissions	- Greenhouse gas emissions (Scope 1+2)¹ - Indirect greenhouse gas emissions (Scope 3) - Percentage of purchased electricity from renewable sources	Climate action Climate action Climate action
Water and resource intensity	- Waste Score - Water Intensity Score	Will be published in the Sustainability Report 2022 as of April 13, 2023 Water management
Water and resource intensity	Wastewater quality	Will be published in the Sustainability Report 2022 as of April 13, 2023

¹The key indicator is used to determine the sustainability factor for the Merck Long-Term Incentive Plan (LTIP).

Roles and responsibilities

Our Executive Board has Group-wide responsibility for our sustainability strategy. It has adopted our three strategic goals. In 2030, we will achieve human progress for more than one billion people through sustainable science and technology. By 2030, we will integrate sustainability into all our value chains. And by 2040, we will achieve climate neutrality and reduce our resource consumption (details can be found under "[Strategy](#)").

The Group Corporate Sustainability unit is responsible for developing and shaping the sustainability strategy and it informs the Executive Board at least once a year about the progress made and the need for action. It is part of the Group function Corporate Sustainability, Quality and Trade Compliance (SQ), which reports to the Chair of the Executive Board. Consequently, overarching Executive Board responsibility for Environment, Social, Governance (ESG) also lies with the Chair of the Executive Board.

Group Corporate Sustainability is also responsible for coordinating the Merck Sustainability Board (previously Corporate Sustainability Council), which was set up in 2022. The Merck Sustainability Board is chaired by the Head of SQ and consists of representatives from our business sectors and from key Group functions, such as Procurement, Communications, as well as Controlling and Risk Management.

The Sustainability Board steers and monitors the Group-wide implementation of the sustainability strategy. It aligns the strategy with the individual business strategies, defines priorities and specifies globally applicable sustainability guidelines. In addition, the Sustainability Board ensures that the initiatives of our various business sectors, Group functions and subsidiaries align with our global sustainability strategy. Moreover, it recommends corresponding initiatives to the Executive Board. Within their respective area of responsibility, each Executive Board member is also responsible for sustainability, reviews the priorities that have been set, and decides on the implementation of initiatives.

In 2022, the Sustainability Board met nine times by video conference. The participants addressed the following topics: Implementing the sustainability strategy in the business sectors, key indicators for measuring and steering sustainability within the company, lowering greenhouse gas emissions, and supply chain due diligence requirements.

An external expert committee for sustainability issues has been supporting our company since 2021. The Merck Sustainability Advisory Panel (MSAP) consists of six independent experts on sustainability-related topics from several institutions worldwide. They advise the members of the Sustainability Board on selected issues and assess the sustainability of our company's business models as well as planned activities. Moreover, they provide their external insights to help address societal and political challenges and developments that could be strategically relevant for our businesses. This panel is chaired by the Head of SQ.

Topics for the non-financial statement

Pursuant to section 289c para 3 of the German Commercial Code, we are obligated to review topics for their double materiality. The principle of double materiality requires companies to disclose non-financial information as soon as the following two criteria are met: Firstly, the information makes it possible to understand how the company's business activities affect non-financial aspects. And secondly, the information is necessary to understand the company's course of business, results of operations and economic position. In 2022, we examined the topics identified within the scope of a [materiality analysis](#) in accordance with the Global Reporting Initiative standards (GRI) for their double materiality.

The following topics achieved the relevance threshold for double materiality in 2022. They cover fiscal year 2022 and pertain to our entire Group. Any deviations from the reporting framework are indicated on a case-by-case basis.

Aspect	Topic
Environmental matters	• Environmental management
	• Climate action
	• Water management
	• Plant, process and transport safety
	• Chemical product safety
Employee-related matters	• Attracting and retaining talent
	• Diversity, equity and inclusion
	• Health and safety
Social matters	• Sustainable supply chains (including the mica supply chain)
	• Patient safety
	• Prices of medicines
	• Clinical studies
	• Bioethics
	• Digital ethics
Respect for human rights	• Data protection and security
	• Human rights
Anti-corruption and anti-bribery	• Governance and compliance (including anti-corruption anti-competitive behavior)
	• Responsible marketing
	• Interactions with health systems
Other topics	• Sustainable innovation and research & development

As part of our approach to comprehensive risk and opportunity management, we also identify current and potential risks and opportunities resulting from environmental, social and governance aspects. This includes tracking information on the gross risks in terms of potential damage and probability, as well as the residual net risks remaining after mitigation measures have been executed. As of the reporting date and pursuant to the risk analysis of the material non-financial topics, no significant risks within the meaning of section 289c (3) sentence 1 No. 3 and 4 of the German Commercial Code (HGB) from the company's own business activities or from business relationships are known that are very likely to have or will have serious negative effects on non-financial aspects. Additional risks are described in the [Report on Risks and Opportunities](#) in the combined management report.

Environmental matters

Environmental protection

Minimizing negative environmental impacts and taking meaningful climate action requires a holistic approach while also constantly monitoring practices and performance. Our goal is to decouple business growth from negative environmental impacts wherever possible. Our production sites are located in established industrial and commercial zones. Before acquiring a company – and thus its facilities – we first conduct an environmental risk assessment, taking into consideration information from publicly accessible sources such as local residents and non-governmental organizations (NGOs).

Roles and responsibilities

The Chair of the Executive Board and CEO of our company is responsible for environmental protection, which also covers climate action, water management, waste and recycling, biodiversity, and plant and process safety. Her duties include the approval of overarching Group-wide guidelines such as our EHS Policy. Furthermore, the Merck Sustainability Board (MSB) monitors the Group-wide implementation of environmental protection goals.

The Group function Corporate Sustainability, Quality and Trade Compliance (SQ) is responsible for steering all the related measures globally. SQ senior leadership approves operational standards and regularly reports on environmental protection to the Executive Board. Every year, SQ prepares a comprehensive environment, health and safety report that covers topics such as climate action, water management, waste and recycling, and plant and process safety. The Executive Board uses this report to steer the strategic direction and as verification for our ISO 14001 certifications. Additionally, the Executive Board receives a monthly update so that measures can be adjusted in a timely manner.

Within our business sectors, the Operations Leadership Committee (OLC) makes strategic decisions on issues pertaining to emissions, energy, water, and waste topics. This body consists of representatives from Life Science, Healthcare and Electronics as well as from SQ. Decisions made by the OLC and any resulting actions are implemented by the respective business sector. Once per quarter, the OLC members update their leaders on matters relating to environmental protection, and this information, if relevant, is then shared with the MSB.

Our commitment: Standards and standard operating procedures

Our approach to environmental management is founded on our Group **[EHS \(Environment, Health and Safety\) Policy](#)**, which has been approved by our Executive Board. Aligned with the requirements of the chemical industry's **[Responsible Care® Global Charter](#)** and the ISO 14001 environmental management standard, this policy underscores our leaders' responsibility for environmental stewardship and health and safety. It is also aimed at our suppliers, calling on them to likewise adopt higher standards of environmental sustainability and safety. Our EHS policy thus complements the **[Supplier code of conduct](#)** (formerly Responsible Sourcing Principles) of our Group Procurement function. Through our Contractor EHS Management Standard we aim to ensure that our contract partners also take environment, health and safety aspects into account.

Potential EHS risks posed by acquisitions, divestments or site closures are assessed within the scope of due diligence, a process defined in our EHS Due Diligence and Post Merger Transaction Standard. We prioritize new sites when performing audits.

Material investments in environmental impact mitigation

Efforts to prevent and monitor air, water and soil emissions entail significant expense on our part, as does proper waste disposal. Moreover, we set up provisions for groundwater and soil remediation to ensure that we can execute all the necessary measures. As of December 31, 2022, our **[provisions for environmental protection](#)** totaled € 148 million, 94% of which was attributable to Merck KGaA, Darmstadt, Germany.

Assessing environmental impacts

As a matter of principle, we conduct risk-based assessments along with audits of all our production facilities every three years with the goal of analyzing and minimizing our environmental footprint. Conducted by Corporate Sustainability, Quality and Trade Compliance (SQ), these assessments serve to ensure that our requirements are being met, with appropriate corrective measures being implemented as needed. In our Group EHS audits, we assess our sites' performance on a five-tier scale ("excellent", "good", "satisfactory", "poor" and "critical"), which in turn determines how frequently audits are conducted. If the findings are deemed to be good, we audit the facility less often, while significant violations can increase the frequency. In 2022, we commissioned a total of 41 audits, which were conducted either virtually or on site. Almost all audited sites received either a "good", "satisfactory" rating, one site was rated "poor" and no sites were rated as "critical".

Reporting incidents and violations

To review critical situations, near misses and environmental incidents as quickly as possible and take countermeasures, we have a set of reporting procedures in place that allow us to track the respective incident, its degree of severity and all risk mitigation efforts. We record all incidents Group-wide and report them to the Executive Board on an annual basis.

In the event of a major occurrence, our digital Rapid Incident Report System (RIRS) promptly notifies SQ and Group Communications functions, who, if necessary, inform the Executive Board. Major incidents could include fatalities, accidents with multiple casualties, incidents that impact neighboring communities or natural disasters such as earthquakes and flooding. Through the RIRS, we can quickly coordinate with all those involved and inform the other sites immediately of the respective event. In addition, employees as well as external stakeholders can report any violations of our standards to Group Compliance.

In 2022, we recorded two significant incident-related spills. One took place at a production site in Germany, the other one in the USA. In neither case were people injured nor were negative environmental impacts expected, which is why it was not necessary to communicate these incidents to the public.

ISO 14001:2015 Group certificate

Since 2009, our company has held an ISO 14001 Group certificate that requires all production sites with more than 50 employees to implement an environmental management system with predefined indicators such as greenhouse gas emissions and water consumption. Other facilities are not obligated to undergo certification. The annual internal audit reports and management reviews carried out under the Group certificate give us a better overview of how all our sites are performing. In 2022, 95 of our sites worldwide were covered by the **ISO 14001** certificate.

Annual external audits are used to monitor our certifications. As part of a defined sample procedure for the Group certificate, a total of 12 sites were externally audited in 2022, with all audited facilities passing. In addition to external inspections, internal audits serve to ensure Group-wide compliance with our requirements.

Climate action

We want to do our part to preserve the climate and comply with the Paris Agreement on climate change. Therefore, we have set our own objectives:

By 2030, we intend to lower our direct (Scope 1) and indirect (Scope 2) greenhouse gas emissions by 50% compared with 2020. We aim to achieve this mainly by reducing process-related emissions, implementing energy efficiency measures and purchasing more electricity from renewable sources.

In May 2022, this near-term goal for 2030 was approved by the Science Based Targets initiative (SBTi), which independently assesses and approves company targets based on its strict climate science criteria. With this confirmation, we are contributing to limiting global warming to 1.5 °C, thus complying with the requirements of the Paris Agreement.

We also aim to cover 80% of our purchased electricity with renewables by 2030.

Moreover, we aim to reduce our Scope 3 emissions across the entire value chain by 52% (per euro of gross profit) by 2030. This target was also approved by SBTi.

By 2040, we intend to have achieved climate-neutral operations throughout our entire value chain; this target covers our Scope 1, 2 and 3 emissions.

Roles and responsibilities

Corporate Sustainability, Quality and Trade Compliance (SQ) is responsible for overseeing all climate action efforts throughout the Group, with our individual sites and business sectors worldwide implementing the necessary measures at the local level. You can find more information under "[Environmental protection](#)".

Our commitment: Standards and legal frameworks

We have three EHS standards in place to manage energy and process-related emissions consistently across the Group, specifically "Energy Management", "Emissions" and "Emissions of Refrigerants". We utilize an internal audit process to randomly check compliance with all EHS standards.

Emissions reduced further

In 2022, we reduced our greenhouse gas emissions by nearly 10%, emitting a total of approximately 1,667,000 metric tons of CO₂ equivalents (CO₂eq) (2021: 1,843,000 metric tons). Our direct emissions (Scope 1) totaled 1,425,000 metric tons of CO₂eq, with process-related emissions accounting for 1,167,000 metric tons of CO₂eq and fuel use accounting for the remainder. Indirect emissions (Scope 2) totaled roughly 242,000 metric tons calculated according to the market-based method (approximately 377,000 metric tons according to the location-based method). Greenhouse gas emission intensity (Scope 1 and 2) amounted to 0.07 kg of CO₂eq per € of net sales in this period (2021: 0.09).

In 2022, we focused on creating more transparency on our Scope 3 emissions. The Greenhouse Gas Protocol defines 15 categories for Scope 3 emissions from upstream and downstream activities. In 2022, these emissions totaled 6,616,000 metric tons of CO₂eq. Categories 1 and 2 (Purchased Goods and Services and Capital Goods) accounted for 69% of our total Scope 3 emissions in this period.

Total greenhouse gas emissions (Scope 1 and 2 of the GHG Protocol)^{1,2}

metric kilotons	2019	2020 ³	2021	2022 Merck Group	2022 thereof: Merck KGaA
Total CO₂eq⁴ emissions	621	2,028	1,843	1,667	148
thereof:					
direct CO ₂ eq emissions (Scope 1)	341	1,706	1,522	1,425	108
indirect CO ₂ eq emissions ⁵ (Scope 2)	280	322	321	242	40
Biogenic CO₂ emissions	13	13	15	13	0

¹ In line with the Greenhouse Gas Protocol, for all previous years greenhouse gas emissions were calculated based on the current corporate structure as of Dec. 31 of the reporting year and retroactively adjusted for acquisitions or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

² Baseline for our emission targets is 2020.

³ Includes Versum Materials as of 2020.

⁴ eq = equivalent

⁵ The figures presented here have been calculated in accordance with the market-based method.

We have included the following gases in our calculation of direct and indirect CO₂eq emissions:

Direct CO₂ emissions: CO₂, HFCs, PFCs, CH₄, N₂O, NF₃, SF₆.

Indirect CO₂ emissions: CO₂.

Other relevant indirect greenhouse gas emissions (Scope 3 of the GHG Protocol)¹

	2019	2020	2021	2022
Total gross other indirect emissions (metric kilotons CO₂eq²)	339	5,030	5,716	6,616
Purchased goods & services (category 1) ³	n/a	3,040	3,572	4,200
Capital goods (Category 2) ³	n/a	293	291	388
Fuel- and energy-related emissions, not included in Scope 1 or 2 (category 3)	127	102	143	121
Upstream transportation & distribution (category 4) ⁴	n/a	264	264 ⁵	319 ⁶
Waste generated in operations (category 5)	50	85	79	85
Business travel (category 6)	87	32	26	78
Employee commuting (category 7)	75	90	94	99
Upstream leased assets (category 8) ⁷	0	0	0	0
Downstream transportation & distribution (category 9) ⁴	n/a	8	8 ⁵	6 ⁶
Processing of sold products (category 10) ⁸	0	0	0	0
Use of sold products (category 11) ⁴	n/a	1,091	1,213	1,290 ⁹
End-of-life treatment of sold products (category 12) ⁴	n/a	23	23 ⁵	26 ⁹
Downstream leased assets (category 13)	0	2	2	2
Franchises (category 14) ¹⁰	0	0	0	0
Investments (category 15)	n/a	0	1	2

¹ In line with the Greenhouse Gas Protocol, for all previous years greenhouse gas emissions were calculated based on the current corporate structure as of Dec. 31 of the reporting year and retroactively adjusted for acquisitions or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

² eq = equivalent

³ The reported figures contain 95-97% of our total spend. The difference stems from smaller sites that are not integrated in our Group-wide purchase volume data. 2020 data are slightly over-reported (approx. 3%) as the currency conversion factor (USD to EUR) from 2021 was used. Non-categorized spends are distributed pro rate to category 1 and 2.

⁴ Compared to other Scope 3 categories, the screening of the emissions in this category contains more uncertainties. Their impact cannot be estimated more precisely at this time. We are working on improving the accuracy of these data.

⁵ Due to high efforts for data preparation, we reference 2020 data for 2021.

⁶ Since 2022, we have applied a new calculation approach – a mix of primary data, distance-based data and a small share of spend-based data. The previous years' figures have not been recalculated retrospectively.

⁷ Already covered under Scope 1 and 2 emissions

⁸ Our company produces a huge variety of intermediate products for various purposes. Due to their many applications and our customer structure, the associated greenhouse gas emissions cannot be tracked in a reasonable fashion.

⁹ Due to high efforts for data preparation, we partly use 2020 data for 2022.

¹⁰ This category is not relevant for us as we do not operate franchises, i.e. businesses operating under a license to sell or distribute another company's goods or services. Out-licensing in the pharmaceutical sector is not regarded as franchising.

Biogenic emissions (Scope 3), if present, are not being recorded.

Significant spills

	2019	2020	2021	2022
Total number of significant spills	0	0	0	2

Energy efficiency

In 2022, a variety of energy efficiency initiatives helped us save around 3,000 metric tons of CO₂eq at our global headquarters in Darmstadt (1,700 metric tons of CO₂eq in 2021). For instance, we improved heating, ventilation and air conditioning systems and reduced base loads for compressed air systems.

As part of the energy and water efficiency program of our Life Science business sector, we rolled out new tools and governance structures in 2022 to help us assess projects to save energy and water. The energy and water efficiency program had a capital expenditure budget of € 4.6 million in 2022, which we will increase to € 9.3 million in 2023. In 2022, we formally trained 18 Facility, Plant Engineering, and EHS Managers from sites globally on energy management.

Slight decline in energy consumption

We consumed 2,432 gigawatt hours of energy in 2022, compared with 2,454 gigawatt hours in 2021. Our energy intensity relative to sales totaled 0.11 kWh/€ in 2022 (2021: 0.12 kWh/€).

In 2022, we further strengthened our focus on purchasing electricity from renewable sources. In this period, we sourced 47% of our purchased electricity from renewable energies, meaning direct supply contracts and energy attribute certificates (2021: 30%). The share of our total energy consumption by renewable energies increased to 20% in 2022 (2021: 13%).

Energy consumption¹

In GWh	2019	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Total energy consumption	2,178	2,374	2,454	2,432	586
Direct energy consumption	1,288	1,266	1,318	1,294	521
Natural gas	1,222	1,179	1,232	1,188	492
Liquid fossil fuels ²	33	52	48	70	29
Biomass and self-generated renewable energy	33	35	38	36	0
Indirect energy consumption	890	1,108	1,136	1,138	65
Electricity	745	945	958	984	65
Steam, heat, cold	145	163	178	154	0
Total energy sold	0.1	0.2	0.1	0.01	0.0
Electricity	0.1	0.2	0.1	0.01	0.0
Steam, heat, cold	0.0	0.0	0.0	0.00	0.0

In TJ	2019	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Total energy consumption	7,839	8,546	8,834	8,755	2,110
Direct energy consumption	4,637	4,558	4,745	4,658	1,876
Natural gas	4,399	4,244	4,435	4,277	1,771
Liquid fossil fuels ²	119	187	173	252	104
Biomass and self-generated renewable energy	119	126	137	130	0
Indirect energy consumption	3,202	3,989	4,090	4,097	234
Electricity	2,682	3,402	3,449	3,542	234
Steam, heat, cold	520	587	641	554	0
Total energy sold	0.5	0.7	0.4	0.04	0.0
Electricity	0.5	0.7	0.4	0.04	0.0
Steam, heat, cold	0.0	0.0	0.0	0.00	0.0

¹ In line with the Greenhouse Gas Protocol, for all previous years energy consumption has been calculated based on the current corporate structure as of Dec. 31 of the reporting year and retroactively adjusted for acquisitions or divestments of (parts of) companies, or for changes in emission factors (portfolio-adjusted).

² Light and heavy fuel oil, liquefied petroleum gas (LPG), diesel, biodiesel, gasoline and kerosene

We use photovoltaics to produce power at multiple sites.

We currently only record purchased secondary energy – this is primarily electricity and, to a lesser extent, heat/steam/cold. Details on the local energy mix, including the respective percentage of primary energy, renewable energy, etc. are not available. Data on local energy efficiency in electricity or heat generation are not available either. Our production sites are located in countries with a widely varying energy mix.

Water management

To us, sustainable water management means obtaining freshwater or discharging treated wastewater without negatively impacting aquatic ecosystems. We are also concerned with addressing water scarcity. To determine whether a site is located in a water-stressed area, we apply a risk factor of the Aqueduct Water Risk Atlas of the World Resources Institute (WRI). We want to reduce the environmental impact of our wastewater and make our processes more water-efficient. In the medium term, we will also take into account water-related risks that exist in our supply chain when purchasing important raw materials. In the long term, we intend to transparently map water use and environmental impacts throughout the entire life cycle of our products.

To this end, we have defined two targets: First, by 2025, we aim to lower our “Merck Water Intensity Score” by 10% compared to 2020. Second, by 2030, we want to reduce potentially harmful residues in our wastewater below the no-effect threshold; this is a scientifically defined limit below which no negative environmental impacts are expected.

Our regular EHS audits at our production and development facilities also review site-specific water management practices. Our water management efforts focus more heavily on our manufacturing sites than on our administrative facilities because production generally poses a higher risk to aquatic ecosystems.

Roles and responsibilities

The Group function Corporate Sustainability, Quality and Trade Compliance (SQ) is responsible for water management. At our sites, engineers work in close collaboration with our EHS managers to lower water consumption and treat wastewater. Further information can be found under “[Environmental protection](#)”.

Our commitment: Standards and procedures

Our Group-wide Sustainable Water Management Part 1 – Wastewater, Sustainable Water Management Part 2 – Water Use and Sustainable Management Part 3 – Water Risk Management standards detail how we integrate mechanisms of sustainable water management into our management system. All three standards are based on the commitments we made under the [Responsible Care®](#) initiative. At the same time, our [Sustainable water management principles](#) set the framework for the three aforementioned standards.

Our Wastewater Standard defines criteria for assessing our wastewater discharges into the ecosystem. It also helps us to achieve our target as regards trace substances in wastewater from our operations. The Water Use Standard sets out mandatory Group-wide requirements for the responsible consumption of water. The Water Risk Management standard establishes a way for us to manage the risks that arise from direct or indirect water extraction and also covers risks such as contaminated rainwater and flooding. We perform internal EHS audits to verify that our sites comply with our three standards. They are all required to measure and assess the risks and impacts of the hazardous substances in their wastewater. Moreover, they must also analyze withdrawal and wastewater risks and comply with the respective requirements of the local authorities.

Water withdrawn from our own sources

For the most part, we draw water used for our production processes from our own wells and source drinking water from local suppliers. In doing so, we do not want water extraction to impair any protected areas, sensitive ecosystems or habitats. Our aim is to extract less water from our own wells than the amounts approved in our permits. At the same time, we keep an eye on trends that could potentially lead to sources being reclassified in the future.

The cooling water used for our production processes generally runs in a circular system. Depending on regulatory standards and the energy footprint, we sometimes use freshwater for cooling in a once-through system. However, this is only done in regions with high freshwater availability. For certain applications, we treat production wastewater and reuse it. In 2022, we recycled a total of 20.7 million m³ of water (2021: 23.5 m³ of water).

Water withdrawal

millions of m ³	2019	2020	2021	2022 Merck Group	2022 Water stress areas
Total water withdrawal	14.0	14.0	13.5	13.2	0.17
Surface water (rivers, lakes)	1.9	1.8	1.9	1.8	0.004
Groundwater	6.8	6.7	6.3	6.3	0.003
Drinking water (from local suppliers)	5.2	5.4	5.2	5.0	0.160
Rain water and other sources	0.05	0.06	0.06	0.06	0.004

These figures do not include the ground water that we use for safety measures at our Gernsheim site in Germany. Here, the water is fed back directly into natural circulation.

Using water more efficiently

We seek to minimize our impact on water availability in the vicinity of our sites. In 2022, we withdrew 13.2 million m³ of water in total (2021: 13.5 million). Local conditions determine whether a sufficient water supply is available. In our water conservation efforts, we pay particular attention to sites in water-scarce areas. To improve our water efficiency, we have therefore defined an intensity score – the Merck Water Intensity Score. The score relates to the amount of water either purchased or withdrawn from our own wells at a site to the number of hours worked, while taking the local availability of water into account. The Gernsheim site (Germany) is excluded from both the score and our water conservation efforts because we must extract a minimum water quantity from our own wells in order to comply with regulatory requirements. In 2022, we lowered the Merck Water Intensity Score by 8.6% in comparison with the baseline year 2020 (2025 target: 10% reduction).

Our site in Rio de Janeiro conducted a project to reduce water consumption by upgrading the on-site wastewater treatment plant and reusing treated wastewater in the cooling towers. After two years of implementation, the average annual volume of water that is reused is approximately 20,000 cubic meter/year, which contributes together with other water saving measures to a reduction of 33% of total water intake compared to 2020.

Our wastewater

In 2022, we generated a total of 12.4 million m³ of wastewater (2021: 13.3 million). This consisted of around 8.6 million m³ of freshwater, which we discharged into surface waters. 3.8 million m³ was classified as “other water” and was treated at external treatment plants or disposed of in an ecologically sustainable manner.

Wastewater volume

	2019	2020	2021	2022 Merck Group	2022 Water stress areas
Total wastewater volume (millions of m³)	13.2	13.4	13.3	12.4	0.130
Wastewater discharged directly	9.3	9.2	9.5	8.6	0.000
Wastewater discharged to third parties	3.8	4.1	3.8	3.8	0.110

We continuously work to optimize our production streams and purification processes in order to conserve water and minimize residues. An expert has been appointed for each of our business sectors to provide guidance for our sites. Apart from aiming to reduce the amount of pharmaceutical active ingredient residues in wastewater, we expanded our measures to include substances with water-hazardous properties in 2022. All the relevant sites have their own wastewater treatment plants and regularly analyze their wastewater to check for harmful substances.

Plant, process and transport safety

We seek to minimize manufacturing process hazards wherever possible in order to prevent workplace accidents, production outages and chemical spills, which is why we regularly review our approach to plant and process safety and continuously gauge it using our EHS performance indicators.

Moreover, all our shipments are to reach our customers and sites safely, undamaged and with the required safety information. Several of the materials we store and transport are classified as hazardous. The storage of such dangerous goods and the transport thereof – whether by road, rail, air, or water – are governed by global regulations. To minimize risks to people and the environment, we apply strict safety requirements across the Group that also comply with applicable laws. We conduct regular reviews to ensure our own warehouses as well as those of third parties comply with these regulations. In 2022, no third-party audits were conducted due to Covid-19.

Roles and responsibilities

Overriding responsibility for plant, process and transport safety lies with our Group function Corporate Sustainability, Quality and Trade Compliance (SQ), which coordinates plant and process safety for the company and defines Group-wide EHS standards and regulations.

Our commitment: Internal standards and international rules

To ensure safe operation throughout the lifetime of a plant, our Group-wide EHS standards contain specific rules for production plants and processes. These include specifications that determine how special risk analyses and hazard assessments are to be carried out. We have also defined measures for the event of accidental release of chemical substances and for fire protection.

Our Group-wide EHS standards stipulate the safety levels for the storage of hazardous materials at our sites. Along with supplementary standard operating procedures and best practice documents, these EHS standards describe the technology, equipment and organizational infrastructure needed to achieve the appropriate safety levels. Contract warehouses must also adhere to our strict safety requirements. Before we sign a contract with an operator, they must submit a statement detailing how they meet our prerequisites. Our Group-wide EHS standards also define the technical and organizational requirements for such warehouses.

Our Group Transport Safety Standard is based on the United Nations Recommendations on the Transport of Dangerous Goods. This guideline is especially important for sites in countries with inadequate local regulations covering the conveyance of hazardous materials.

Assessing potential risks

Before commissioning a plant, we draft a safety concept, which is subject to continuous review throughout the entire lifetime of the facility. It is updated as needed until the facility is decommissioned. This safety concept contains an overview of potential risks and specifies corresponding protective measures. In the event that alterations are made to a plant, we reassess the hazard and risk situation. Our Risk Management Process guides all our sites in identifying and assessing risks and serves to devise further measures to minimize them.

We use internal EHS audits to complement the inspections conducted by our EHS and dangerous goods managers in order to ensure that our sites comply with process, plant, transport, and storage safety regulations. Normally, these audits are conducted every three years at production sites and every four years at warehouse and distribution sites. If major shortcomings are identified, we re-audit the respective site the following year. Conversely, we may decide to extend the period between audits at facilities where, based on the findings from previous audits, we deem the potential risk to be low. Our sites are required to rectify any deficiencies discovered during the audit, with the auditor subsequently checking whether the specified corrective actions have been taken. In 2022, we conducted 41 EHS audits in accordance with our Group-wide EHS standards.

Keeping a close eye on safety

We track EHS performance indicators at all production and warehouse facilities, as well as at major research sites, including both accidents and near misses. We investigate each individual incident and then devise appropriate countermeasures in an effort to reduce the likelihood of such events reoccurring in the future. EHS performance indicator data are reported once a month within each business sector, with the Executive Board receiving reports on the topic once per year. Four indicators are particularly important to us:

- Under our EHS Incident Rate (EHS IR), we track and evaluate all major and minor accidents and incidents as well as further EHS-relevant incidents. The EHS IR covers both our own employees as well as those of contractors. To calculate it, we state the number of incidents and the severity of the event in relation to the number of hours worked. The lower the EHS Incident Rate, the safer the site is. In 2022, the ratio was 2.8 (2021: 3.9). The significantly lower rate is attributable to the fact that we have now fully included all office sites in the assessment.
- The EHS IR also includes our Loss of Primary Containment (LoPC) indicator. In 2022, we recorded two significant incident-related spills. One took place at a production site in Germany, the other one in the United States. In neither case were people injured nor were negative environmental impacts expected, which is why it was not necessary to communicate these incidents to the public.
- The EHS Leading Rate (EHS LR) reflects the number and the results of the analyses of near misses and critical situations.
- For the Lost Time Injury Rate (LTIR) we set ourselves the goal of bringing our Group-wide LTIR below 1.0 by 2025 (number of accidents Group-wide resulting in at least one missed day of work per million hours worked). In 2022, our LTIR of 1.2 remained unchanged in comparison with the previous year.

Chemical product safety

Product safety is one of our top priorities. During the product development phase, we investigate the potential adverse impacts of chemical substances. Along the entire value chain of our products – from raw materials to manufacture and commercialization – we provide relevant information on their hazardous properties and how to deal with them. These instructions facilitate the safe handling and use of our products in line with all regulatory requirements. We publish this information primarily on the relevant digital channels. As paper safety data sheets are still common in some countries, we can also provide these upon request through our customer service.

Roles and responsibilities

Our Life Science, Healthcare and Electronics business sectors have organizational structures to implement our product safety strategy in line with their respective business requirements and customer needs. This approach includes registering chemicals, classifying hazardous substances, and highlighting risks using safety data sheets, labels and digital communication tools.

Our Group standards provide a framework for governing the set-up of effective operational processes for product safety, hazard communication and chemicals regulatory compliance throughout our business sectors. In addition, the Group Chemicals Regulations Council fosters cross-sectoral alignment of strategic regulatory activities required for existing and emerging chemicals regulations as well as sustainability and identifies potential impacts for our company.

This approach also applies to innovative fields of development such as nanomaterials, which we use with the greatest of care in line with the precautionary principle. Furthermore, our Group-wide [Policy for Use and Handling of Nanomaterials](#) provides the necessary guidance on the use of these materials.

Legal requirements and internal guidelines

Our internal guidelines define the roles, responsibilities and basic processes required to comply with national and international regulations. In addition, we have also endorsed voluntary commitments of the chemical industry such as the [Responsible Care® Global Charter](#). Using the [Globally Harmonized System](#) for Classification and Labelling of Chemicals (GHS) for hazard communication allows us to streamline our internal processes and provide consistent, harmonized, and high-quality information to our customers.

In 2022, there were no incidents of non-compliance with regulations specifically concerning potential health and safety impacts and the labeling of our chemical products.

Safety analysis of our products

Safe and sustainable by design implies that product safety starts during development. Therefore, at an early stage of our product development process, we analyze innovations in terms of their impacts on human health and the environment. We continuously evaluate the intrinsic hazards of both our existing and new products to create relevant product safety information in line with all applicable rules.

Product safety information

Chemical product safety is all about protecting human health and the environment from adverse impacts resulting from the use of chemical products throughout their life cycle. To achieve this, we provide all relevant information to our customers and the public, which helps to raise awareness of the hazards and build a greater understanding of how to mitigate risks and use the products safely.

To obtain all the relevant information on hazard profiles, we employ industry-standard digital tools that gather all information available on the substances we use.

Employee-related matters

Attracting and retaining talent

To ensure our ongoing success, we are focusing on the future by creating meaningful impacts and building needed capabilities. At the same time, we must respond to changing demographics and adapt to the behaviors and expectations of the highly competitive talent market. Therefore, in 2022, we enhanced our talent acquisition strategy with a more personal, employee-focused approach. Our goals include reinventing our talent sourcing approach to build targeted and integrated pipelines and effectively recruiting diverse talent to our organization.

We have designed our compensation structure to provide valuable benefits to our employees and their families. Our reward system recognizes the uniqueness of our employees while providing flexibility wherever possible. Through our competitive compensation structure, we aim to be attractive to future employees in particular. Additionally, our international employee mobility programs create an environment suited to the needs of a rapidly evolving workforce.

We have revised our talent retention approach by tailoring our retention efforts more strongly to different target groups and countries as well as striving to create an inclusive environment that sparks our employees' creativity and growth.

Total number of employees¹

As of Dec. 31	2019	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Total number of employees	57,071	58,127	60,348	64,243	8,485
Men	32,531	33,204	34,274	36,452	5,510
Women	24,540	24,923	26,074	27,791	2,975

¹ Merck also has employees at sites that are not fully consolidated subsidiaries. These figures refer to all people directly employed by Merck and therefore may deviate from figures in the financial section of this report.

Employee age by region

As of Dec. 31

Number of employees	Worldwide	North America	Europe	Merck KGaA	Asia-Pacific (APAC)	Latin America	Middle East and Africa (MEA)
2021							
Up to 29 years old	9,129	2,219	3,341	1,125	2,912	482	175
thereof: women	4,359	961	1,598	415	1,437	265	98
30 to 49 years old	36,157	6,939	15,653	4,288	10,260	2,404	901
thereof: women	15,888	2,958	7,224	1,550	4,081	1,225	400
50 or older	15,062	4,912	8,223	2,668	1,113	643	171
thereof: women	5,827	1,881	3,276	824	356	231	83
Average age	41.6	43.9	43.1	43.1	37.1	40.8	39.7
Total employees	60,348	14,070	27,217	8,081	14,285	3,529	1,247
2022							
Up to 29 years old	9,926	2,753	3,530	1,181	2,999	476	168
thereof: women	4,637	1,178	1,655	441	1,441	264	99
30 to 49 years old	38,423	7,811	16,216	4,549	11,174	2,333	890
thereof: women	16,909	3,278	7,528	1,664	4,498	1,196	409
50 or older	15,894	5,283	8,498	2,755	1,239	681	192
thereof: women	6,245	2,045	3,437	870	412	255	96
Average age	41.6	43.3	43.1	43.1	37.3	41.1	40.3
Total employees	64,243	15,847	28,244	8,485	15,412	3,490	1,250

Internationality of employees

As of Dec. 31	2019 ¹	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Number of nationalities	139	141	142	139	83
Number of nationalities in management positions (Role 4 or above)	73	75	79	78	34
% of non-Germans in management positions (Role 4 or above)	64	66	66	66	13

¹ In 2019, the position assessment had not yet been carried out for employees of Versum Materials as well as of Allergopharma.

New employees

As of Dec. 31	2019 ¹	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Total number of new employee hires	7,924	6,669	8,960	10,682	647
by age group					
up to 29 years old	3,432	2,889	3,679	4,314	318
30 to 49 years old	4,055	3,347	4,610	5,397	302
50 or older	437	433	671	971	27
by gender					
Women	3,622	3,016	4,101	4,569	252
Men	4,302	3,653	4,859	6,113	395
by region					
Europe	2,529	2,160	2,567	3,015	647
North America	1,733	1,789	2,855	3,971	not applicable
Asia-Pacific (APAC)	2,729	2,206	2,803	3,071	not applicable
Latin America	578	396	579	460	not applicable
Middle East and Africa (MEA)	355	118	156	165	not applicable
Rate of new employee hires² (%)	14	11	15	17	8
by age group³					
up to 29 years old	43	43	41	40	49
30 to 49 years old	51	50	51	51	47
50 or older	6	7	8	9	4
by gender³					
Women	46	45	46	43	39
Men	54	55	54	57	61
by region³					
Europe	32	32	29	28	100
North America	22	27	32	37	not applicable
Asia-Pacific (APAC)	34	33	31	29	not applicable
Latin America	7	6	6	4	not applicable
Middle East and Africa (MEA)	5	2	2	2	not applicable

¹ These figures exclude the approximately 2,400 Versum Materials and Intermolecular employees who are not classified as new hires because they joined Merck as part of the acquisitions.

² Formula for calculating the rate of new employee hires: Total number of new employee hires divided by number of employees at the end of the fiscal year.

³ Formula for calculating the rate of new employee hires by age/gender/region: New employee hires of the focus group divided by the total number of new employee hires.

Staff turnover^{1,2}

	2019	2020 ³	2021	2022 Merck Group	2022 thereof: Merck KGaA
Total turnover rate	9.07	8.22	10.82	10.16	2.58
Turnover rate by gender					
Men	8.69	8.22	10.69	10.40	2.66
Women	9.54	8.22	11.00	9.93	2.44
Turnover rate by age group					
Up to 29 years old	13.13	11.30	16.64	15.91	2.99
30 to 49 years old	8.90	7.74	10.05	9.55	2.26
50 or older	7.03	7.52	9.22	8.05	2.94
Turnover rate by region					
Europe	5.72	5.64	6.00	5.91	2.58
North America	11.02	9.79	15.44	14.33	not applicable
Asia-Pacific (APAC)	13.18	10.60	14.66	12.84	not applicable
Latin America	13.47	11.40	12.95	13.38	not applicable
Middle East and Africa (MEA)	12.14	11.80	16.57	13.04	not applicable
Total number of leavers	4,863	4,721	6,354	6,358	215
by gender					
Men	2,621	2,697	3,575	3,673	144
Women	2,242	2,024	2,779	2,685	71
by age group					
Up to 29 years old	1,042	974	1,451	1,542	35
30 to 49 years old	2,898	2,677	3,545	3,569	100
50 or older	923	1,070	1,358	1,247	80
by region					
Europe	1,500	1,490	1,601	1,640	215
North America	1,264	1,281	2,078	2,182	not applicable
Asia-Pacific (APAC)	1,484	1,394	2,015	1,905	not applicable
Latin America	459	398	449	467	not applicable
Middle East and Africa (MEA)	156	158	211	164	not applicable

¹ The table contains unadjusted turnover rates. The rate excludes employees who pause due to parental leave or a long-term illness, as well as employees who are transitioning to the non-working phase of partial retirement.

² The employee turnover rate is calculated as follows: Total number of leavers from the past 12 months divided by the average employee headcount multiplied by 100.

³ The figures do not reflect the approximately 500 Allergopharma employees, who were not included in the employee turnover rate due to the divestment of the business.

In 2022, the average length of service for employees Group-wide was 9.2 years (2021: 9.5 years), with 15.4 years (2021: 15.7 years) for Merck KGaA employees.

Roles and responsibilities

Group Human Resources (HR) supports and advises all business sectors and Group functions within our organization regarding our human capital, especially topics related to recruiting, vocational training and advanced training. Across all our sites, HR employees work with leaders from various functions and business sectors to employ strategies that engage our people in line with Group-wide HR guidelines and requirements, including attractive compensation models and benefits. Every two to three years, we conduct internal audits to ensure that we implement our guidelines effectively.

The Chair of the Executive Board and CEO is responsible for Group Human Resources. Our Chief HR Officer, who leads the HR function and oversees all our HR activities, reports directly to her. Our Business Services unit oversees the operational tasks of HR work, such as drafting contracts and payroll accounting. The Chief Financial Officer is responsible for this unit.

Our commitment: Group-wide policies and guidelines

As set down in our [Social and Labor Standards Policy](#), we will respect our employees' legal rights to form and join worker organizations of their own choosing, including labor organizations and trade unions, and will not discriminate based on an employee's decision to join or not join a labor organization.

Our High-Impact Culture is founded on six behaviors (obsessed with customers and patients; act as the owner; be curious and innovate boldly; simplify and act with urgency; raise the bar; disagree openly, decide and deliver). We regularly inform executives and employees about these behaviors through global campaigns.

Our People Development and Learning Policy provides a Group-wide framework that guides employees in managing their professional growth. It defines requirements for our development opportunities, roles and responsibilities. The associated processes are described in our People Development and Learning Standards. Our flexible work guideline details our approach to evolving work environments and our aspiration to create a more agile organization.

A competitive compensation structure

We reward the performance of our employees in order to maintain a competitive edge in attracting qualified professionals. Within our Group, we base compensation on the requirements of each position and each employee's respective performance. We make no distinctions based on gender or any other diversity criteria.

To ensure we maintain a competitive compensation structure, we regularly review our compensation policy based on data analyses and industry benchmarks. This enables us to compare internal factors and market requirements in equal measure. Before making changes to our compensation structure, we consult with key stakeholders such as employee representatives. In 2022, we introduced a sustainability factor into our Long-Term Incentive Plan (LTIP). More information on the LTIP can be found in the [Compensation report](#).

Strengthening our sustainability culture

We launched two e-learning courses in order to strengthen the sustainability culture in our company. The first one is for employees and was already rolled out at the end of 2021. The second one has been available since September 2022 and is targeted to managers with personnel responsibility. The two courses are mandatory for the relevant employees and are available in nine and seven languages, respectively. As of the end of 2022, 83% of all employees had completed the training.

Diversity, equity and inclusion

We are committed to promoting a strong sense of inclusion among our employees. Therefore, we approach diversity, equity & inclusion (DE&I) with the same purpose as our other global business objectives and aspirations. While we have always been a diverse organization – we currently span 66 countries and have over 64,000 employees from 139 nationalities – we recognize that our success depends on our ability to foster an environment that champions equity and inclusion. In addition, our DE&I approach fuels our efforts to make positive impacts in the communities where we live and work. We expect our leaders and managers to be mindful and considerate in how they attract, hire, retain, and promote their people. We aim to help every employee maximize their potential, regardless of their gender identity, culture, ethnicity, race, religion or creed, sexual orientation, nationality, socioeconomic and family status, language, disability status, age, mindset, faiths, military service, or political conviction.

We strive to create equitable outcomes and identify and eliminate any barriers that may hinder our employees' contributions or their access to opportunities or career advancement. Ultimately, we believe diversity inspires progress and strengthens our ability to innovate in all areas of our business.

Number of employees by hierarchical level¹

As of Dec. 31	2019 ²	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Total employees	57,071	58,127	60,348	64,243	8,485
Senior management (Role 6+)	190	193	194	191	66
Middle management (Role 4 & 5)	3,352	3,637	3,831	4,018	886
Low management (Role 3)	9,499	10,286	10,880	11,877	2,277
Other employees (below Role 3)	44,030	44,011	45,443	48,157	5,256
% of women (total)	43	43	43	43	35
thereof: in senior management (Role 6+)	39	42	49	51	18
thereof: in middle management (Role 4 & 5)	1,146	1,284	1,413	1,550	281
thereof: in low management (Role 3)	4,029	4,352	4,669	5,123	879
thereof: other employees (below Role 3)	19,326	19,245	19,943	21,067	1,797
% of men (total)	57	57	57	57	65
thereof: in senior management (Role 6+)	151	151	145	140	48
thereof: in middle management (Role 4 & 5)	2,206	2,353	2,418	2,468	605
thereof: in low management (Role 3)	5,470	5,934	6,211	6,754	1,398
thereof: other employees (below Role 3)	24,704	24,766	25,500	27,090	3,459
by age group					
Up to 29 years old (%)	15	15	15	15	14
thereof: in senior management (Role 6+)	0	0	0	0	0
thereof: in middle management (Role 4 & 5)	8	6	8	12	5
thereof: in low management (Role 3)	190	199	241	263	61
thereof: other employees (below Role 3)	8,362	8,365	8,880	9,651	1,115
30 to 49 years old (%)	60	60	60	60	54
thereof: in senior management (Role 6+)	69	68	63	58	24
thereof: in middle management (Role 4 & 5)	1,933	2,032	2,172	2,235	525
thereof: in low management (Role 3)	6,516	6,926	7,298	8,007	1,495
thereof: other employees (below Role 3)	25,859	25,948	26,624	28,124	2,505
50 years or older (%)	25	25	25	25	32
thereof: in senior management (Role 6+)	121	125	131	133	42
thereof: in middle management (Role 4 & 5)	1,411	1,599	1,651	1,771	356
thereof: in low management (Role 3)	2,793	3,161	3,341	3,607	721
thereof: other employees (below Role 3)	9,809	9,698	9,939	10,382	1,636

¹ Merck also has employees at sites that are not fully consolidated subsidiaries. These figures refer to all people directly employed by Merck and therefore may deviate from figures in the financial section of this report.

² In 2019, the position assessment had not yet been carried out for employees of Versum Materials as well as of Allergopharma. In the figures, employees whose positions have not been assessed have been allocated to "other employees (below Role 3)".

Roles and responsibilities

The Chief Diversity, Equity and Inclusion Officer is responsible for our global DE&I strategy and steering its related activities. In this role, she reports directly to the Chair of the Executive Board, whose Board responsibilities include Group Human Resources. In addition, we have established a centralized Diversity Council consisting of high-ranking executives from all our business sectors and selected Group functions.

Our commitment: Industry-wide initiatives and regulations

Our **Social and Labor Standards Policy** categorically states that our company does not tolerate any form of discrimination, physical or verbal harassment, or intolerance. To underscore our commitment to equality, fairness, inclusion, and tolerance in the workplace, we also participate in industry-wide initiatives:

- **Women's Empowerment Principles**
- Inclusion Action Plan of the German Mining, Chemical and Energy Industrial Union (**IG BCE**)
- Equal Opportunity Charter
- German Diversity Charter, **Charta der Vielfalt e. V.**

Strategy rollout and new structure introduction

In 2022, we rolled out our DE&I strategy globally. We created a network comprising our 18 major countries, nominated dedicated representatives and developed tailored roadmaps for each country. We also streamlined the councils and working groups in the business sectors and major Group functions, renaming them Diversity, Inclusion, Community & Equity Councils.

In 2021, we pledged to our people, partners, patients, and industry to intensify our DE&I efforts and set robust aspirations to hold ourselves accountable. In 2022, we continued this strong focus and demonstrated that we are on track to advance toward our 2030 goals.

Gender equity

We developed measures to achieve a more balanced gender structure at various hierarchical levels of our business. We are steadily making progress and have increased the share of women in leadership (roles 4+) to 38% (2021: 36%) while maintaining a stable 43% proportion of women in our global workforce. Building on this effort, we are aiming for gender parity in leadership positions by 2030. Moreover, we are committed to fair and equitable pay for all employees.

Culture and ethnicity

With 24% of our employees based in the United States, it is crucial that we become an employer of choice among underrepresented racial and ethnic groups in this market. Therefore, we plan to increase the share of employees in U.S. leadership (roles 4+) who are members of underrepresented racial and ethnic groups from 21% to 30% by 2030.

Additionally, due to our current performance and future growth in Asia, Latin America and the Middle East and Africa (MEA), accounting for 40% of our Group sales, we aim to increase the global share of nationals from Asia, Latin America, and MEA in leadership positions (roles 4+) from 16% to 30% by 2030.

Inclusion

Beyond our aspiration to foster specific types of diversity and equity, we are accelerating our efforts to create a genuinely inclusive culture for all employees. To achieve this, we rolled out training courses to help leaders reflect on how they can lead more inclusively. All leaders will be encouraged to complete these courses over the coming years. At the end of 2022, 64% (2021: 37%) of our leaders had participated in this training program.

Committed to fair and equitable pay

Our commitment to pay equity is a critical aspect of our DE&I strategy. To create transparency around unexplained pay gaps and identify their underlying root causes, we conducted a pay equity analysis in 2021 with a focus on gender-based discrepancies. In this first step, we analyzed ten of our largest countries, covering approximately 80% of our total employees. Based on this analysis, we continued to improve our transparency by releasing pay data publicly for the first time: The identified adjusted (unexplained) gender pay gap is less than 1.5% in favor of men. While this is a good starting point and below the existing benchmark, we will continue to monitor pay data and take measured actions as needed. These include enabling our leaders to ensure we continue making equitable and unbiased pay decisions.

Ensuring fair treatment for all

We do not tolerate any form of discrimination in our company, as stipulated with binding effect in our [Code of Conduct](#) and [Social and Labor Standards Policy](#). In 2022, we published two new position papers on [non-discrimination](#) and [non-harassment](#), complementing our [position paper on DE&I](#). In addition, we have established various reporting channels to ensure employees have a clear point of contact should they experience harassment or discrimination in the workplace, or any other violations of our standards. Their first

points of contact are their supervisors, HR or compliance teams. Alternatively, employees can also make anonymous calls to our compliance hotline. In 2022, 20 alleged cases of discrimination were reported via the compliance hotline and other channels, seven incidents were confirmed.

Health and safety

We seek to promote the health and well-being of our employees and sustain their long-term performance ability, which in turn necessitates a safe workplace. We are therefore constantly working to further strengthen our health and safety culture.

The lost time injury rate (LTIR) is the indicator used to gauge the success of our occupational safety efforts. It is a global measure of the number of accidents resulting in at least one day of missed work per one million hours worked. We determine the Group-wide LTIR both for our employees and supervised temporary staff. Our objective is to lower LTIR to below 1.0 by 2025.

Generally, before starting an activity anywhere in the world, we perform a hazard assessment to identify risks and do everything possible to eliminate them before commencing the activity or commissioning a plant. If this is not feasible, we put measures in place to minimize the likelihood of risks and their potential impacts. Hazard assessments are the responsibility of our individual sites and are therefore conducted by them.

Since the start of 2022, we have been developing a Group-wide health strategy for our employees to enable them to maintain and promote their health.

Roles and responsibilities

Our EHS (Environment, Health and Safety) management system is the responsibility of Corporate Sustainability, Quality and Trade Compliance, which in turn reports to the Chair of the Executive Board. This Group function sets objectives, oversees the respective initiatives globally and conducts internal EHS audits. Local EHS managers and their teams ensure that our individual sites comply with all occupational health and safety laws and regulations. They are also responsible for local projects, campaigns and programs.

Employees concerned about their health or safety are permitted to temporarily step back from their work until the issue has been resolved. Globally, across the Group, they are encouraged to report such concerns via our [compliance hotline](#).

Our commitment: Standards and policies

Our Corporate [EHS Policy](#) (Corporate Environment, Health and Safety Policy) describes our fundamental approach to occupational health and safety. It is an integral part of our EHS management system and undergoes an external ISO 45001 audit every year. As part of a [Group certificate](#), our occupational health and safety management system was ISO 45001-certified at 61 sites at the end of 2022.

Our Group-wide Health Policy specifies our approach to ensuring workplace safety for our employees while also promoting their health and well-being. In this policy, we set out our Group-wide approach to health and safety management, which is aimed at preventing workplace accidents and occupational illnesses.

It is our aim to ensure that environmental, health and safety aspects are also respected in our partnerships with contractors throughout the entire relationship, from starting a job to completion. This objective is reflected in our Contractor EHS Management Standard.

Accident rates

Our employees are required to immediately report any relevant occupational accidents to Corporate Sustainability, Quality and Trade Compliance, where the incidents are assessed. If necessary, we then implement additional safety measures at our sites. This procedure is now practiced across all of our production facilities around the world. We track the following occupational safety data across our sites worldwide:

- The LTIR measures the accidents resulting in at least one day of missed work per one million hours worked. In 2022, our LTIR of 1.2 remained unchanged in comparison with the previous year. The majority of incidents resulting in lost time were slips, trips and falls, along with contusions and lacerations from the operation of machinery and equipment. Once more, in 2022, we recorded no fatal accidents.
- We use our Environment, Health and Safety Incident Rate (EHS IR) to [track accidents](#).
- Alongside this indicator, in the United States we also use the Occupational Illness Rate to monitor work-related illnesses and their long-term effects.

Work-related accidents¹

	2019	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Lost Time Injury Rate (LTIR = workplace accidents resulting in missed days of work per one million hours worked)	1.6	1.3	1.2	1.2	2
by region					
Europe	2.6	2.4	2.1	1.7	2
North America	1.0	0.8	1.2	1.7	not applicable
Asia-Pacific (APAC)	0.2	0.1	0.1	0.3	not applicable
Latin America	1.7	0.8	0.4	0.6	not applicable
Middle East and Africa (MEA)	0.0	0.4	0.0	1.1	not applicable
Number of deaths	0	0	0	0	0
by region					
Europe	0	0	0	0	0
North America	0	0	0	0	not applicable
Asia-Pacific (APAC)	0	0	0	0	not applicable
Latin America	0	0	0	0	not applicable
Middle East and Africa (MEA)	0	0	0	0	not applicable
by gender					
Women	0	0	0	0	0
Men	0	0	0	0	0

¹ Including supervised temporary staff

A work-related accident is an injury that results from the type of work, in the course of doing said work, and that has no internal cause. Work-related accidents are considered relevant if they occur on the premises, on business trips, during goods transport, as a result of external influences (e.g. natural disasters), or due to criminal acts involving personal injury. Commuting accidents and accidents during company sporting activities are not included. First-aid incidents are generally not included in the LTIR since these usually do not result in more than one day of missed work.

Clear rules of conduct

Group-wide, all new EHS managers must complete a three-day EHS onboarding that covers topics such as occupational health and safety as well as our BeSafe! safety culture program. Through this initiative, we raise employee awareness of occupational hazards and teach them rules for safe behavior. In addition, we regularly provide occupational safety training at our sites covering both legal requirements as well as the specific local risks.

Social matters and respect for human rights

Responsible supply chain

With our supplier management endeavors, we aim for compliance with fundamental environmental and social standards in addition to high quality, reliable delivery and competitive prices. Therefore, we have introduced relevant strategies, processes and guidelines to prevent violations of supply chain standards and continuously improving our sustainability performance. Unless stated otherwise, the approaches presented apply to direct suppliers. Furthermore, our supplier management activities include special measures particularly for indirect suppliers working in the area of conflict minerals.

To achieve our [sustainability goals](#), our Group Procurement team is working closely with our suppliers. We aim to create transparency in all our sourcing regions and fully integrate sustainability into all our value chains. To this end, we have defined two key indicators to measure our journey towards increasing this transparency by evaluating the sustainability performance of our relevant suppliers with valid sustainability assessments. Our definition of valid sustainability assessment includes assessments carried out over the last three years and performed by a reliable, approved source. Relevant suppliers either indicate a specific country and industry risk or contribute to a significant percentage of our supplier spend (at least 50%). For the risk evaluation, we previously used the risk data provided by EcoVadis. For the country risk, we have developed our own more comprehensive country risk score in 2022.

In 2022, 46% (2021: 33%) of our relevant suppliers were covered by a valid sustainability assessment; 82% (2021: 74%) of our spend generated from these suppliers were covered by suppliers with a valid sustainability assessment. To achieve comparability of our key indicators over the years, we applied this new country risk score also retrospectively for 2021 data, the starting point of our measurement.

We consider all applicable legal requirements and initiate corresponding measures where necessary. For this purpose, in 2022, we implemented measures to operate compliant with [German Supply Chain Due Diligence Act](#). Among other things, the Head of Corporate Sustainability, Quality and Trade Compliance has been appointed as Human Rights Officer.

Our Supplier Decarbonization Program is a key element of achieving our [Science Based Target](#). Through the program, we aim to reduce greenhouse gas emissions associated with purchased goods and services as well as capital goods.

Risk management process

To ensure security of supply, we select our suppliers based on criteria such as country risk, material risk, supplier risk, and their strategic importance to the business. This process helps our sourcing managers identify potential mitigation actions with relevant suppliers and supports them in making improvements. The approach towards our strategic suppliers which account for approximately 49% of our total supplier spend includes the identification, monitoring and assessment of supply security risks. It comprises four main elements:

- Supplier Risk Assessments: to capture the overarching risks at the supplier level, considering multiple risk domains.
- Alert system: to notify our Procurement organization about risk events arising with any of our suppliers.
- Material Risk Assessments: to identify and mitigate the risks of the materials used in our most significant finished products.
- Risk Response Tracker: a system to create and monitor risk mitigation activities in inter-disciplinary teams.

We calculate risk factors for suppliers and raw materials by multiplying risk probability and risk impact. We have simplified our risk methodology to focus on the ten most relevant risk categories - including but not limited to economic freedom, social unrest, unfair business practices, and poor labor practices - grouped into three risk domains. We also include criteria for identifying supplier relationships impacted by key sustainability risks, such as mineral sourcing and animal welfare.

Due diligence process for responsible sourcing of minerals

We source and sell products that contain minerals commonly referred to as “3TG” (tin, tungsten, tantalum, gold – collectively also known as conflict minerals). These minerals involve the risk of being extracted, traded, handled, and exported from conflict-affected and high-risk areas where human rights are not always respected and violations thereof need to be prevented.

Our aim is to source materials in a responsible and conflict-free manner and not to contribute to adverse impacts through our activities. Therefore, we have a due diligence program that applies across all our business sectors and is in line with applicable laws and international standards.

In order to continuously improve our due diligence practices, we have a system to store and maintain supplier information across our business sectors. This system supports increased transparency of our supply chain. In addition, we are working on the integration of further control mechanisms into our due diligence framework for high-risk suppliers.

Roles and responsibilities

Group Procurement is responsible for integrating sustainability requirements into the relevant stages of our sourcing and supplier management processes. Our Center of Excellence for Supply Security coordinates the relevant measures, such as updating our guidelines where necessary, examining processes and coordinating our participation in external initiatives.

Our commitment: Guidelines and standards

We expect all our suppliers and service providers to comply with our environmental and social standards, which are primarily derived from the [core labor standards](#) of the International Labour Organization (ILO) and the [UN Global Compact](#). We expect our suppliers to ensure that their subcontractors respect the same rules. In the reporting year, we have developed a [Supplier Code of Conduct](#) which details our expectations towards suppliers and business partners regarding human rights, health and safety, business integrity, environmental protection, continuous improvement, and management of their respective suppliers more comprehensively. It replaces our Responsible Sourcing Principles as of January 2023.

Our [Responsible Minerals Sourcing Charter](#) demonstrates our commitment to responsible sourcing of minerals from conflict-affected and high-risk areas. It applies to all our legal entities and subsidiaries worldwide. The charter complements the requirements set out in our Supplier Code of Conduct.

To ensure that we work based on industry standards and can rely on comparable data analytics and expert analysis, we collaborate with our peer companies in industry initiatives. For example, we are a member of Together for Sustainability ([TfS](#)), the Pharma Supply Chain Initiative ([PSCI](#)), the Responsible Mica Initiative, and the Responsible Minerals Initiative ([RMI](#)). We call on our suppliers to let us or trusted partners conduct assessments or audits to increase our supply chain transparency and identify fields of activity to improve sustainability performance or mitigate infringement risks.

Together for Sustainability supplier assessments and audits

Through the TfS initiative, suppliers are assessed either based on information obtained during audits or based on self-reported and publicly accessible information provided by EcoVadis, an independent rating agency. [EcoVadis](#) assesses suppliers from more than 160 countries and 200 sectors across the four categories of

Environment, Labor and Human Rights, Ethics, and Sustainable Procurement. On top of the assessments, suppliers are also monitored through a 360-degree news watch. The results are shared among TfS member companies in compliance with all restrictions stipulated by antitrust law.

Through the TfS initiative alone, we have access to more than 1,700 valid scorecards on the assessment of our suppliers, more than 1,100 of which completed a new assessment or re-assessment in 2022. In some cases, these were initiated by us and in other cases by other TfS members.

Mica supply chain

Mica is an important raw material for our effect pigments, which are used in automotive, cosmetic and industrial coatings as well as plastics. We procure the majority of our mica from the Indian states of Jharkhand and Bihar. We have special measures in place to comply with high social and environmental standards in our mica supply chain. By procuring mica from the Indian states of Jharkhand and Bihar, where social and economic factors contribute to poor working conditions, including child labor, we are supporting this region by safeguarding local employment and livelihoods. We source the raw material only from suppliers operating in formal working environments and we monitor compliance with our standards, including the prohibition of child labor.

Our mica suppliers are informed of our standards and have confirmed that they adhere to the principles of our [Human Rights Charter](#) as well as the requirements of our [Supplier Code of Conduct](#) (formerly Responsible Sourcing Principles). In the event of non-compliance with our standards, we work with suppliers to ensure the appropriate implementation of corrective measures.

We do not tolerate child labor and contractually prohibit our suppliers from employing children. If one of our suppliers were found to be using child labor, Merck would terminate the business relationship immediately. We are driving initiatives and taking measures to improve the conditions of mica sourcing based on our high standards. We continuously review our monitoring processes to improve their effectiveness.

Auditing our mica supply chain

We have implemented a series of oversight mechanisms using a system that monitors and audits conformity with our social and environmental standards. In addition to visits by our company's employees, regular inspections are conducted by third parties, who conduct comprehensive announced audits as well as frequent, unannounced verification visits.

Environmental Resources Management ([ERM](#)), a leading global provider of environmental, health, safety, risk, and social consulting services, conducts external audits of mines and processing plants, investigating working conditions as well as environmental, health and safety issues. The audit reports document any identified shortcomings in this respect and propose corrective actions. Findings concerning the ventilation of workplaces and fire prevention were successfully addressed. Our employees in Kolkata (India) and Darmstadt (Germany) take action to address any identified issues. If the corrective measures are not respected, we may suspend or even terminate our business relationship.

Since 2013, IGEP Consult, an Indian non-governmental organization, has conducted regular unannounced inspections to review labor standards throughout our supply chain. During these visits, IGEP officials monitor occupational safety and compliance with laws preventing child labor. In 2022, its inspections focused on checking the availability of physical examinations for workers and conducting mock fire drills. Additionally, we regularly optimize the escalation process together with IGEP, which holds bi-weekly review meetings with representatives of our company to assess suppliers. These meetings help to identify any required actions, which our sourcing teams then discuss and implement with our suppliers. As a result, our suppliers have successfully improved the working conditions at these sites.

Evaluating and tracking mica sources

We use a tracking system to help ensure that the mica we purchase is derived from sources qualified by our company. We also use this tracking system to monitor productivity of our mica sources. Based on written records of the daily extraction quantities, we review the volumes of mica reported and supplied to the processing facilities. Furthermore, we use a digital traceability solution to increase transparency in the mica supply chain.

To maintain accuracy, our processes undergo constant review and improvement. We are also evaluating other mica sources in accordance with our quality, social and environmental standards, both in India and other regions. For example, in 2022, we sourced a considerable amount of mica in Brazil, where we have also established oversight mechanisms to monitor and audit adherence to these standards.

Human rights

We are committed to upholding human rights, which is why we became a signatory to the [UN Global Compact](#) back in 2005. We endeavor to prevent the risk of human rights violations as far as possible, not only at our own sites but also along our entire supply chain. That is why we integrate human rights due diligence into our business processes.

We view our human rights due diligence as a continuous process, which we constantly adapt and improve. This also prompts us to continually review our approach. We closely monitor regulatory developments – for example, the planned EU directive on human rights due diligence.

Roles and responsibilities

Our Executive Board has ultimate responsibility for human rights within our sphere of influence. The Executive Board exercises this responsibility by requiring our Managing Directors to respect human rights.

Our Group Corporate Sustainability unit is responsible for coordinating all human rights due diligence activities across the Group. The persons responsible for these issues in the respective Group functions, business sectors and local units implement the specific measures, for instance by integrating human rights due diligence into existing processes.

Our commitment: Guiding principles, charters and laws

Our [Human Rights Charter](#) aligns with the [UN Guiding Principles on Business and Human Rights](#). It is our overarching human rights governance document and defines the relevant requirements for our company. We expect our employees as well as our suppliers and all companies with which we have business ties to comply with this charter.

In 2022, we further developed our existing approach to human rights due diligence, prompted by the specific requirements of the new German Supply Chain Due Diligence Act. Among other things, we appointed the Head of Corporate Sustainability, Quality and Trade Compliance as human rights officer to monitor compliance with human rights due diligence requirements and the implementation of processes throughout the Group in the future.

Identifying actual and potential impacts on human rights

We perform risk assessments to understand the potential impacts our operations and business relationships could have on human rights. For instance, we investigate human rights risks at our sites as well as risks related to product and service sourcing. These risk assessments enable us to derive the corresponding strategies and measures. We track human rights risks through our strategic supplier risk process. More information on how we engage with suppliers can be found under [Responsible supply chain](#).

We also meet our human rights due diligence obligations when deploying new technologies. Our [Code of Digital Ethics](#) defines digital ethics principles and forms the basis for the work of the Digital Ethics Advisory Panel. More information can be found under [Digital ethics](#).

Auditing our suppliers and sites

Our [Global Social and Labor Standards Policy](#) stipulates the social and labor standards at our sites. We regularly check compliance with the requirements using a risk-based approach. Among other things, this takes into account risks that may arise if relevant laws and regulations change or if there are violations of internationally recognized labor rights by governments and companies, as assessed by the [International Trade Union Confederation](#) and documented in the annual ITUC Global Rights Index. If we identify a violation during the audit, we define remedial actions together with the responsible Managing Director and/or local HR staff.

In addition, we review human rights aspects at our sites through security audits. The audits are one control mechanism of our security governance framework. Increased risk transparency and centralized CAPA tracking allows us to ensure that our sites meet security-relevant human rights aspects.

Through the Together for Sustainability (TfS) initiative, we determine whether our strategically important [suppliers](#) comply with human rights standards.

Creating awareness among our employees

To train our Managing Directors and senior management, we offer an e-learning course on implementing the requirements of our Social and Labor Standards Policy in their areas of responsibility. Our onboarding training for all new EHS managers continues to cover the topic of human rights, with a particular focus on the issue of modern slavery. In addition, the Supervisory Board received training on the requirements and implementation of the new German Supply Chain Due Diligence Act in 2022.

Our reporting practices

We inform the public about our approaches, measures and results of human rights due diligence. We provide information on this annually in our Sustainability Report. Additionally, legislation in Australia and the United Kingdom requires us to publish the steps we are taking to counter forced labor and human trafficking. Apart from the [UK Modern Slavery Statement](#), we also published our first [Merck Australia Modern Slavery Statement](#) in 2022. Both have been signed by the Chair of the Executive Board and published on our website.

Our complaint mechanism

Our [compliance hotline](#) is the most important channel for reporting complaints about potential human rights violations. Our employees as well as external stakeholders can report suspected cases via this Group-wide whistleblowing system in their respective national language, free of charge and anonymously, either by telephone or a web-based application. We thoroughly investigate all complaints that we receive and take countermeasures if necessary. More information on the compliance hotline can be found under [Compliance management](#).

In 2022, there were no indications from our compliance hotline of child or forced labor or violations of the right to collective bargaining or freedom of association within our own global business operations. Regarding forced labor, we were informed that we offered rubber gloves for which a manufacturer is accused of labor abuses including forced labor in Malaysia. The matter is being investigated further. Our supplier has already terminated business relations with the manufacturer. Consequently, our company also no longer has any business ties to the manufacturer in the affected supply chain.

Human rights violations¹

	2019 ²	2020	2021	2022
Number of reported violations of Social and Labor Standards Policy	-	108	121	136
Number of confirmed Violations of Social and Labor Standards Policy	-	29	41	68
thereof: number of incidents of discrimination	-	2	6	7

¹ In 2020, we modified our reporting structure for human rights violations. Previously, we reported on such violations in the "Reported compliance violations" table. Since 2020, we report on violations of our Social and Labor Standards Policy, which was implemented across the entire Group in 2019.

² Due to our revised reporting practices, we have decided not to report the data from previous years.

Patient safety

Through a rigorous benefit-risk management process, we help to ensure that the benefits of our medicinal products always outweigh the risks for patients. Every new medicine goes through a series of precisely defined development stages. Before any medicinal product is administered to human subjects, we conduct extensive preclinical testing both in vitro and in vivo.

During clinical development, we diligently use all the collected data to continuously evaluate the medicinal product's benefit-risk profile. If we consider the medicinal product's benefit-risk profile to be positive, we then submit an application for marketing authorization to the relevant regulatory authorities.

Continual monitoring of product safety risk profiles

Once we launch a new medicinal product, the number of patients being treated with the product increases significantly. In rare circumstances, there may be adverse and potentially serious effects that were not detected during clinical development, which is why we continuously monitor risks and assess the benefit-risk profiles of the products after their market launch. Pharmacovigilance includes the process of monitoring a medicinal product on an ongoing basis to detect and assess safety signals as part of signal management activities. Our pharmacovigilance system and our pharmacovigilance business continuity management ensure continuous monitoring of adverse effects, allowing us to proactively and transparently minimize and communicate any risks. Emergency response procedures for business continuity are managed in accordance with global and local business continuity plans, tested in regular, defined intervals or with mock scenarios. In addition, we always provide healthcare professionals and patients with the latest information on the safety of all our marketed medicinal products. The scope of continuous safety monitoring includes the entire life cycle of a product, ranging from development, market launch and commercialization to expiration of the marketing authorization.

Roles and responsibilities

Our Global Patient Safety unit is responsible for pharmacovigilance. It continuously collects current safety data from a wide variety of sources across the globe, including clinical studies, early access programs, spontaneous reports on adverse effects, patient support programs, and articles published in medical and scientific journals. Our vision is to embed a deep knowledge of safety into early decision-making as we evolve to practice predictive safety.

Our experts help to ensure that all information on the risks and adverse effects of our medical products is properly documented, tracked and reported to the respective health authorities in accordance with regulatory requirements. Our Global Patient Safety unit analyzes all data and reassesses the benefit-risk profile based on these data, where required. We then inform regulatory authorities, healthcare professionals and patients about new risks, additional risk mitigation measures and potential changes in the benefit-risk profile.

Our Global Patient Safety unit hosts a Pharmacovigilance Intelligence Council that focuses on changes in pharmacovigilance legislation and its impacts on our global and local pharmacovigilance systems. This initiative enables us to make strategic decisions and govern changes in pharmacovigilance requirements, which fosters our target to ensure continuous compliance with regulatory requirements.

Our Medical Safety and Ethics Board

Our Medical Safety and Ethics Board (MSEB) oversees the safety and benefit-risk assessments of our medicinal products throughout their clinical development and commercialization. This internal board is chaired by our Chief Medical Officer and comprises experienced physicians, scientists and experts from our company. Throughout a medicinal product's entire life cycle, the MSEB reviews and assesses important medical safety risks and benefit-risk issues and endorses appropriate measures to minimize risks, such as updates to product information. The MSEB furthermore reviews human-related ethical issues as appropriate.

Our commitment: Guidelines and statutory requirements

Our aim is to follow international guidance and standard procedures, such as the International Council for Harmonisation ([ICH](#)) guidelines and the Good Pharmacovigilance Practices (GVP) established by the European Medicines Agency ([EMA](#)) and national health authorities. Furthermore, we aim at complying with all new statutory pharmacovigilance regulations in the countries where we market our products.

Inspections and audits for drug safety monitoring

Regulatory authorities conduct periodic inspections to verify that we comply with statutory requirements as well as our own internal pharmacovigilance standards. We follow up on the findings of health authority inspections and take necessary actions to ensure the ongoing compliance of our pharmacovigilance system. In 2022, we had four pharmacovigilance inspections.

Furthermore, we perform audits to ensure that all our units and subsidiaries involved in pharmacovigilance consistently meet all global requirements. In 2022, we conducted a total of 19 pharmacovigilance audits and found no significant deviations in our pharmacovigilance systems from these requirements and standards. We also conducted 16 external audits at our vendors and licensing partners involved in pharmacovigilance, helping us improve our pharmacovigilance processes and comply with regulatory requirements.

Applying our proactive safety strategy to benefit-risk assessments

With regard to product safety risk assessments, we have implemented an improved benefit-risk management strategy in order to become a proactive and benefit-risk-focused organization. In this context, we developed in 2021 the concepts and principles for conducting benefit-risk assessments at each stage of product development and post-marketing. Along with the implementation of the redesigned benefit-risk strategy, the new Benefit Risk Action Team co-leadership model was rolled out in 2022. This redesigned approach will enable us to understand in even greater detail the benefit-risk profiles of our products, enabling early decision-making within the organization to protect patient safety. Ultimately, the aim is to be able to provide the right medicine to the right patient at the right time.

Up-to-date labeling and product information

Our product information explains to healthcare professionals and patients how to correctly use the respective product and make informed treatment decisions. We review and update all product information documents, such as package leaflets, to ensure our medicinal products contain the latest information on safety, efficacy and pharmaceutical formulation. In accordance with regulatory requirements, we submit all modifications to our leaflets to the respective regulatory authorities for approval. In 2022, there were no significant reportable incidents of non-compliance with regulations concerning the labeling of our medicinal products.

Internal and external training

Our pharmacovigilance experts are regularly trained so that they gain and maintain the required experience and knowledge to carry out their activities. We manage our training via a global learning platform and verify compliance with our training requirements by producing training completion reports.

Our approximately 24,000 Healthcare employees receive basic pharmacovigilance training once a year that covers the procedure for reporting adverse effects or special circumstances associated with the use of our products.

Prices of medicines

To help ensure that all patients have access to the most effective medicines for their needs, we are working to prevent cost from becoming a barrier to treatment. Therefore, we adapt our medicine prices according to people's ability to pay in different geographic and socioeconomic segments.

We are committed to fair, flexible and sustainable pricing – both within and across countries. We therefore adapt our prices based on local market considerations, such as unmet medical and treatment needs, health system capacity, infrastructure and socioeconomic standards. This approach involves working closely with governments and other stakeholders. In addition, we continuously monitor dynamic healthcare environments and markets, pricing and reimbursement systems as well as legal and regulatory guidelines, adjusting our prices as necessary.

We conduct price analyses annually to validate price thresholds and provide guidance on local pricing to our subsidiaries for the following year. The aim is to ensure they meet patient access needs, taking a consistent, data-driven approach. We also make our products affordable to patients in low- and middle-income countries with an equitable value and access strategy that includes participating in government tenders, providing flexible pricing, establishing high-quality affordable brands or branded generics and operating patient access programs.

Furthermore, we support innovative risk-sharing agreements and are working to improve data efficiency in health systems in order to achieve an optimal distribution of funds and resources.

Roles and responsibilities

Our Global Market Access and Pricing (GMAP) unit evaluates market launch prices in coordination with the respective franchises. The team reports directly to a member of our Healthcare Executive Committee. The GMAP unit systematically evaluates our medicine portfolios and applies equal access initiatives to them. Our local affiliates are responsible for managing prices and adapting them to evolving local conditions in compliance with our pricing governance and the defined price approval process.

Our commitment: Medicine price guidelines and principles

The affordability of our health solutions is part of our broader patient value proposition. Our medicine pricing adheres to the stipulations of our overarching [Access to Health Charter](#) and is defined in detail in an internal guideline. Additionally, our Patient Access Programs Policy sets out standards for offering medicines at affordable prices.

Value-based contracting models

We are committed to advancing value-based healthcare through pricing and contracting mechanisms that fully comply with all applicable local laws and regulations. In collaboration with payers, such as health insurance companies, we have developed various product- and market-specific reimbursement and contracting models. These help to provide patients with prompt access to our innovations. In addition, we aim to pilot outcome-based contracting models in one or two markets for our Fertility product portfolio in 2023.

Equitable value and access approaches to serve low- and middle-income patients

We work in close partnership with governments and other stakeholders on innovative, differential medicine pricing schemes. In addition, we supply products at affordable prices to certain countries in Africa, Asia, Latin America, and the Middle East.

Our pharmaceutical tender excellence initiative offers a strategic tender framework. This includes a web-based system that helps country teams increase quality and agility in tender decisions, while improving performance tracking and collaboration.

For some of our existing high-quality products, we have created second brands at affordable prices, particularly in countries with a large percentage of patients with very low incomes. We operate patient access programs that enable us to offer certain products at affordable prices in several countries.

Clinical studies

Our aim is to conduct high-caliber clinical research that always is in compliance with applicable laws and regulations. As a responsible company, we set Group wide requirements to ensure that the highest ethical and scientific standards worldwide are met when conducting clinical trials.

We only conduct clinical studies to investigate issues that are relevant to patients, healthcare professionals or society, and only when the medicines being tested show significant therapeutic promise and have a positive benefit-risk ratio. In addition, a sound, established scientific methodology must be available to investigate these scientific or medical questions. We only enroll the specific number of participants required to answer each of these questions.

Protecting the safety, well-being, dignity and rights of the patients and healthy volunteers participating in our clinical studies is of utmost importance to us. We do not intentionally expose study participants to undue risk or irreversible harm. Personal data privacy is also very important to us, and we maintain a strong focus on data protection and confidentiality in compliance with statutory regulations.

Based on our Standard on Human Research we aim to design and plan our studies to ensure that diverse patient populations who are expected to use a product when approved are adequately represented. Study participants shall not be discriminated against due to e.g. gender, ethnic origin, religion, disabilities, sexual orientation or socio-economic status.

Patient-focused drug development

We are improving our approach to research and development by committing to patient-focused drug development that more actively involves patients, caregivers, and their advocates in our work. Their valuable insights into disease and treatment management will help us make more informed decisions at each stage of the medicine development process. We aim to make our studies easy for patients to understand while ensuring all participants have positive experiences as they contribute to our understanding of the particular disease and its treatment. At every level of our organization, we are additionally educating staff about the value of a close, more consistent patient interaction and the requirements to protect our patients' independence and privacy.

We conduct all our clinical studies in accordance with local laws and regulations, and we adhere to all relevant international scientific and ethical standards, irrespective of the region or country.

Roles and responsibilities

Clinical drug development, including clinical studies and the related governance process, are the responsibility of our Global Development unit. The Head of Global Research & Development reports to the CEO Healthcare, who is a member of the Executive Board.

We have established two internal committees to oversee our clinical studies. The Integrated Protocol Review Committee is responsible for the studies performed by the company on medicines that are under clinical development, while the Global Medical Decision Board is responsible for our own studies with approved medicines, as well as for all studies performed by independent investigators and supported by us (so-called investigator-sponsored studies). Both bodies consist of medical-scientific experts and executives with long-standing experience in clinical research.

Before administering a new drug to humans, there must be sufficient evidence that it offers a potential therapeutic benefit, is sufficiently safe for use in humans and has a positive benefit-risk ratio. We only take the critical step of a first-in-human clinical trial after diligently conducting extensive preclinical testing. The decision lies with a separate committee, the Human Exposure Group, chaired by our Global Chief Medical Officer.

We continuously analyze potential risks for study participants before and during our clinical studies. Our Medical Safety and Ethics Board (MSEB) oversees the safety of the participants in our clinical studies and, as necessary, reviews the benefit-risk profiles of investigational drugs.

Our commitment: International guidelines and requirements

Our Human Subjects Research and Development Policy provides the framework for conducting clinical studies and helps ensure that we adhere to all applicable legal, ethical and scientific standards. In addition to the relevant national laws and regulations, these standards also include:

- The [Good Clinical Practice](#) (GCP) guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ([ICH](#))
- The [Declaration of Helsinki](#), published by the World Medical Association
- The [Belmont Report](#) by the [U.S. Office for Human Research Protections](#)
- Good Pharmacovigilance/Laboratory/Manufacturing/Distribution Practices (GVP/GLP/GMP/GDP)
- The [International Ethical Guidelines for Health-related Research Involving Humans](#), published by the Council for International Organizations of Medical Sciences ([CIOMS](#))
- The [Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases](#) and the [Joint Position on the Publication of Clinical Trial Results in the Scientific Literature](#), published by the International Federation of Pharmaceutical Manufacturers & Associations ([IFPMA](#)), the European Federation of Pharmaceutical Industries and Associations ([EFPIA](#)), the Japan Pharmaceutical Manufacturers Association ([JPMA](#)), and the Pharmaceutical Research and Manufacturers of America ([PhRMA](#))
- The [Principles for Responsible Clinical Trial Data Sharing](#), published by EFPIA and PhRMA, and the IFPMA Principles for Responsible Clinical Trial Data Sharing

Regular supervision of clinical studies

Our clinical study processes and procedures are regularly inspected by relevant regulatory authorities to verify their compliance with applicable laws and guidelines.

The Research & Development Quality unit applies a risk-based identification strategy to determine areas that need to be audited. Quality assurance audits are performed internally within Healthcare R&D (for example, process audits) and externally (for example, at vendors' sites and investigational sites). We respond immediately to observations during audits by investigating their root causes and, according to their criticality, defining and implementing corrective and preventive actions to improve processes, prevent reoccurrence of irregularities and ensure compliance.

A hybrid auditing approach combining remote and on-site audits was successfully implemented and most of the audits of the Annual Audit Plan 2022 were completed as planned.

Conducting clinical studies responsibly

Every clinical study follows defined procedures to ensure it is conducted to the highest quality standards in line with good working practices (GxP) for the development and manufacturing of drugs, the ethical principles of the [Declaration of Helsinki](#) and other international guidelines and regulations. In 2022, regulatory authority inspections did not unveil issues which had a significant impact on patient rights, patient safety, or the data integrity of a study.

Disclosure of clinical studies and publication of results

We are obligated to disclose findings from our clinical studies. We do this publicly in a complete, accurate, balanced, transparent, and timely manner as laid out in our Clinical Trial Disclosure Policy. We publish results from our clinical studies in medical journals in line with applicable laws and industry codes. In this way, we adhere in particular to the current version of the Good Publication Practice ([GPP3](#)) and follow the recommendations of the International Committee of Medical Journal Editors ([ICMJE](#)). Our [Standard on Clinical Trial Data Transparency](#) underscores our strong commitment in this matter.

Enabling early access to new medicines

Not all patients have the opportunity to take part in a clinical study and must therefore wait for a new pharmaceutical product to be approved. Through our Early Access Program, we can, under specific circumstances, enable patients to gain early access to new, potentially life-saving medicines. The offer is aimed at people with serious conditions who have already received all available therapies without success. It allows them to be treated with medicines that have already been clinically tested but have not yet been approved. Furthermore, we offer patients who participated in one of our clinical studies post-study access to the investigational product, provided that certain conditions are met. Here, too, we meet stringent statutory, ethical and scientific standards. By performing a thorough assessment of all available data, we ensure that the potential benefits outweigh the potential risks for patients.

Bioethics

Our goal is to conduct research in an ethically responsible manner and to develop ethical frameworks that guide us in making forward-looking business decisions. Patient benefit and well-being are always our top priority, whether in clinical studies, treatment with our medicines, or the distribution of our products to academic researchers and the biopharmaceutical industry. We carefully evaluate our positions when it comes to controversial topics.

Roles and responsibilities

Since 2010, the Merck Ethics Advisory Panel for Science and Technology has been issuing clear recommendations on scientific and technology topics involving ethical questions as well as issues extending beyond pure bioethics, in line with our transformation into a science and technology company. Co-chaired by two of our leading scientific experts from our senior management team, the MEAP provides recommendations that guide our actions and business activities. In addition to renowned international experts from the fields of bioethics, medicine, philosophy, law, and the natural sciences, the panel also consists of technology and sustainability experts. The MEAP receives its mandate from the Executive Board.

The MEAP meets multiple times a year and can also be convened on an ad-hoc basis in response to emerging urgent ethical issues. The meeting minutes can be accessed on our intranet, along with the recommendations issued by the MEAP. Our employees can also submit topics for discussion to the panel. In addition, they may report ethical concerns through our [compliance hotline](#) or by reaching out to our Bioethics team.

Our Stem Cell Oversight Committee (SCROC) was established on the recommendation of the MEAP back in 2013. This committee reviews and approves all planned in-house research activities involving the use of human stem cells, ensuring compliance with legal requirements as well as our ethical guidelines. This also includes joint projects with external partners. The committee consists of internal experts from our business sectors as well as external professionals from the fields of bioethics, medicine and law.

In 2022, we expanded the range of consulting services on ethics issues. Our goal is to also take ethics perspectives into account when making forward-looking business decisions. To this end, we launched the Ethics Foresight project, in which external experts and selected MEAP members support our employees from the business units on strategically relevant ethical issues.

Our commitment to policies and standards

Our [Genome Editing Principle](#) provides a mandatory ethical and operational framework for our employees. This is complemented by additional guidelines that define how we conduct research and business in an ethical manner. Our [Stem Cell Principle](#) sets the ethical boundaries for the use of human stem cells in our research. Our [Fertility Principle](#) regulates our research in fertility treatment and in-vitro-fertilization.

Use of genome-editing technologies

CRISPR/Cas9 opens up new possibilities in genetic engineering research that could bring about major advances in the treatment of serious diseases. Laws in different countries allow for a varying degree of latitude in applying this technique. Bioethical positions on germline editing have been evolving for years through academic and social discourse. Our position on human germline editing is as follows:

“In accordance with the German Embryo Protection Act, we do not support the use of genome editing in human embryos and clinical applications of germline interventions in humans. We recognize that there may be value in responsibly conducted related research.”

Stem cell research

We neither participate in clinical programs that utilize human embryonic stem cells or cloned human cells for the treatment of diseases, nor do we pursue such approaches ourselves. However, we use human embryonic stem cells in our research and offer our customers several select stem cell lines. In both applications, we only allow the use of human embryonic stem cells if clearly defined conditions have been met. For instance, we only utilize stem cells for research purposes if our SCROC has reviewed the respective project and given approval. In 2022, review and approval were granted in one case. We exclusively make use of cell lines that have been approved by the United States National Institutes of Health ([NIH](#)) and are allowed under the German Embryo Protection Act as well as the German Stem Cell Law.

Digital ethics

As it is our aim to develop and use new digital technologies responsibly, we promptly identify any ethical issues that may arise from algorithm-driven and data-based business models. Since 2021, the Merck Digital Ethics Advisory Panel (DEAP) has been focusing on complex ethical issues surrounding digital technologies and supports that our digital business model follows a holistic, ethical approach.

Roles and responsibilities

The DEAP discusses ethical issues arising from our digital applications and business activities, especially in the healthcare sector. One of its main tasks is to help ensure that we develop digital innovations responsibly while addressing potential digital ethics questions that could result from collecting and processing data as well as from the use of these digital technologies.

The panel, which issues recommendations on our actions as a company, consists of external international science and industry experts from the fields of digital ethics, law, Big Data technologies, digital health, medicine, and data governance. In addition, we involve bioethics experts as well as representatives from patient organizations as needed. The DEAP receives its mandate from the Executive Board and our employees may submit topics for the panel to discuss. Summary minutes of DEAP meetings and the recommendations made will be available on our intranet from 2023 onwards, provided that they do not contain any confidential business information. The panel held four meetings in 2022, focusing on ethical challenges that could result from our business model for bioelectronics.

Our commitment: Guidelines and standards

As a company, we want to position ourselves with respect to digital ethics. We are therefore developing clear ethical standards in this new field, primarily for critical areas, for instance handling health data, doing so in collaboration with various stakeholders and experts.

Together with the DEAP, we apply our Code of Digital Ethics (**CoDE**), in order to address issues pertaining to the ethical use of data and algorithms. The CoDE serves as a guideline for our digital business models, a tool for analyzing ethical challenges and a basis for practical DEAP recommendations. As one of our overarching governance documents, the CoDE applies to all employees and is publicly accessible. In 2022, we developed an employee training course on the CoDE, which we plan to roll out in 2023.

Data privacy and cyber security

The mandate and goal of our Group Data Privacy unit is to mitigate risks and create a global framework for data privacy-compliant business operations. This unit helps to train our employees to handle data responsibly and with clear accountability. It safeguards our company by providing data privacy risk assurance and ensuring compliance with relevant data privacy laws globally. Group Data Privacy also contributes to creating value for the development of digital business models.

It is of critical importance for our business that we protect our information systems, their contents, and our communication channels against any criminal or unwanted activities. These include e-crime and cyberattacks, such as unauthorized access, information leakage and misuse of data or systems. Our goal is to complete the implementation of a global and consistent data privacy management system by mid-2023.

Roles and responsibilities

Group Data Privacy is an independent function, organizationally integrated into Group Compliance and Data Privacy. We have a Group Data Privacy Officer and a network of local Data Privacy Officers at various sites Group-wide. In line with external regulations, the Data Privacy Officers and their respective teams act independently and without receiving internal or external instructions. Group Data Privacy regularly prepares data privacy updates and a comprehensive data privacy report. This report is submitted to the Executive Board and the Supervisory Board.

Cyber Security is part of our Group Corporate Security Office. In addition, we have a Group Chief Information Security Officer and a network of Information Security Officers within the business sectors, each in turn supported by dedicated networks. The individual sectors hold risk ownership and act as our first line of cyber security defense. Our Global Cyber Security function acts as a second line of defense and has responsibilities regarding cyber security risk governance and oversight. Our third line of defense comprises internal audits.

New Cyber Security organization

At the beginning of 2022, we created a new Cyber Security organization with a mandate to improve trust and strengthen resilience against cyberattacks and data breaches.

Our Cyber Security team defines policies and standards for cyber security (including data security) while providing oversight, tools and systems to manage and monitor our overall cyber security risk exposure. The team is also responsible for providing 24/7 cyber security monitoring and incident response capabilities across the entire company environment as well as training employees across the organization on how to protect data appropriately.

Our commitment: Guidelines and standards

Our Data Privacy Policy and the corresponding standards and procedures define our principles for processing personal data. This approach allows us to achieve a high level of data protection for our employees, contract partners, customers, and suppliers as well as patients and participants in clinical studies. Our Group-wide understanding of data privacy is based on European legislation, in particular the European Union General Data Protection Regulation (EU GDPR). We are also taking steps to meet local data privacy requirements, where these are stricter than our Group-wide standards.

Our Group Cyber Security governance framework comprises organizational, process-related and technical information security countermeasures based on recognized international standards. In addition, we apply harmonized electronic and physical security controls (e.g. access control and security monitoring) to bolster our ability to handle sensitive data, such as trade secrets.

Training and IT tools

In line with the EU GDPR and our global approach to data privacy, we regularly conduct e-learning training courses in ten languages. In 2022, the completion rate for our e-learning courses was 98%.

We maintain a central IT tool to provide a single source for data privacy processes, such as registering data processing activities and reporting potential data privacy incidents. In 2022, we rolled out a new data privacy tool. In the reporting year, we registered no sanctioned complaints or incidents concerning breaches of customer privacy, data leaks, theft, or loss of customer data. In three out of 57 cases, minor personal data breaches were reported to the supervisory authority. These were not sanctioned.

Data Privacy

	2019	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Reported violations of Data Privacy Guidelines	1	3	3	4	1
Customer Privacy¹					
Total number of substantiated complaints received from outside parties	0	0	0	0	0
Total number of complaints from regulatory bodies	1	0	0	0	0
Total number of identified leaks, thefts, or losses of customer data	1	0	0	0	0

¹ These data only reflect incidents classified as significant.

Anti-corruption and anti-bribery

Compliance management

As a global company, we have stringent requirements for effective compliance management. Importantly, we seek to emphasize compliance by acting in line with our [company values](#) and believe that profitable business operations should go hand in hand with the highest ethical standards.

Roles and responsibilities

Our Group Compliance function is responsible for the framework of the following core topics: the Merck Code of Conduct, anti-corruption and anti-bribery (including healthcare compliance, third-party due diligence, transparency reporting), anti-money laundering, antitrust, and conflicts of interest.

To cover these topics, we have Group-wide policies, standards and procedures in place that ensure our business activities comply with the relevant laws, regulations and international ethical standards. Other compliance-related issues, including the respective internal regulations and guidelines, such as [Pharmacovigilance](#), Export and Import Controls, and [Environment, Health, Safety, Security, Quality](#), are managed by the responsible functions.

Our Group Compliance function is responsible for our compliance portfolio, which consists of the following elements:

- Risk Assessment: Identifying internal and external critical risks in regular business operations
- Policies & Procedures: Global policies, procedures and standards to mitigate identified risks
- Compliance Committee/Forums: Platform for compliance-related discussion and decision-making, including relevant key functions
- Training & Awareness: Appropriate training and additional measures to educate and keep awareness high
- Programs & Tools: Comprehensive compliance programs and supporting tools contributing to internal controls and overall governance
- Monitoring & Reporting: Tracking of compliance-related data; perform internal and external reporting
- Case Management: Timely response to reports of misconduct and implementation of corrective actions
- Continuous Improvement: Based on and applying to all compliance program elements

Our Chief Compliance Officer reports on the status of our compliance activities, potential risks and serious compliance violations to the Executive Board and Supervisory Board twice a year at a minimum. As part of our regular reporting processes, we compile a comprehensive compliance and data privacy report annually for the Executive Board. This includes the status of our compliance program, continuous improvement initiatives and key figures on compliance and data privacy cases. Additionally, we prepare a mid-year update to highlight ongoing developments and the status of relevant projects and initiatives.

Our Chief Compliance Officer oversees all Compliance departments and the underlying Compliance Officers and Compliance experts around the world. The Compliance Officers implement our compliance program within their respective areas of responsibility (adapting to local regulations) and receive guidance from our Group Compliance Center of Expertise. This is a centralized body that drives the design and evolution of our compliance program across all business sectors and Group functions.

Our commitment: Guidelines and standards

Our compliance program builds on our company values and integrates these into our compliance framework, which consists of Group-wide policies, standards and procedures for entrepreneurial conduct. The following are mandatory for all our employees:

- [Merck Code of Conduct](#)
- [Human Rights Charter](#)
- Anti-Corruption Standard
- Anti-Money Laundering Group Standard
- Conflict of Interest Policy
- Antitrust and Competition Law Policy
- Compliance Reporting and Investigation Policy
- Dawn Raid Policy
- Standard on Local Compliance Standards
- [Supplier Code of Conduct](#) (formerly Responsible Sourcing Principles)

Risk assessment

Proper compliance risk management is crucial to identify undetected risks and ensure our company remains protected. For this purpose, we are implementing a compliance risk identification process. We started this initiative by launching a global compliance risk process for all our business sectors to improve objectivity and enable a more data-driven risk approach. In addition, we established a comprehensive risk matrix that focuses on bribery and corruption risks, illustrated through in-depth risk categorization and risk scenarios. As a next step, in 2022, we started conducting country-based risk assessments. This approach considers gross and net risks while looking at tangible risk scenarios for the respective business. During this process, Group Compliance works closely with the businesses to enhance their risk awareness and create a better understanding of compliance risks. The first round of this process includes high-risk countries. By 2022, we rolled out a risk identification process to get a better risk overview on bribery and corruption related risks.

Conflicts of interest

We take all potential conflicts of interest seriously. Employees must avoid situations where their professional judgment may come into conflict with their personal interests. They must also disclose every potential conflict of interest to their supervisor and document the disclosure. Such issues are typically resolved directly between the employee and the supervisor but can also be routed to Human Resources, Legal, Compliance, or other relevant functions.

Management and requirements of third parties

For compliance management to be effective, it must not be restricted to the boundaries of our own company. While our [supplier management processes](#) focus on vendor compliance with our standards, our global Third Party Risk Management process governs interactions with sales parties, such as commercial agents, distributors and dealers. We expect our third parties worldwide to adhere to our compliance principles. We collaborate only with parties who pledge to comply with relevant laws, reject all forms of bribery, and adhere to environmental, health and safety guidelines.

We apply a risk-based approach to select the third parties with whom we do business. The greater the estimated risk regarding a particular country, region, or type of service, the more in-depth we examine the third party before entering into a business relationship. We also explore background information from various databases and information reported by third parties.

If we encounter compliance concerns, we further analyze and verify the relevant information. Based on the outcome, we decide whether to reject the potential third party, impose conditions to mitigate identified risks or terminate the existing relationship. By end of 2023, we plan that all subsidiaries of our company will have a new Third Party Risk Management process and tool, for due diligence of all high risk third parties – to conduct business only with those that are legally compliant.

Compliance training

We provide regular compliance classroom and online training courses on our Code of Conduct, anti-corruption, antitrust, data privacy, anti-money laundering, and healthcare compliance standards. We require employees to take these courses based on their exposure to risk. Some courses also apply to independent contractors and supervised workers, such as temporary employees.

We introduced a new Conflicts of Interest e-learning module that explains what conflicts of interests are and how these should be managed within our company. The course is available in nine languages. Furthermore, we launched a new e-learning course to provide an overview of our Third-Party Risk Management and to emphasize the importance of Third-Party Risk Assessments.

Anti-money laundering

We have implemented a global anti-money laundering (AML) program consisting of a global Anti-Money Laundering Group Standard, training and a dedicated process to report and investigate red flags as well as any high-risk transactions. Suspicious transactions are reported to the German Financial Intelligence Unit or other authorities as required.

We aim to continuously improve our AML program. Following a worldwide risk assessment in 2021 to identify jurisdictions imposing the strictest legal and regulatory frameworks applicable to our businesses, we initiated in-depth AML risk assessments for higher-risk jurisdictions. Based on these assessments and constant review of changes in the legal environment, we are implementing stricter local AML programs where required.

Reporting potential compliance violations

We encourage all employees worldwide to report potential compliance violations to their supervisors, Legal, HR or other relevant departments. Globally, they can also use our central whistleblowing compliance hotline free of charge and anonymously to report violations in their local language by telephone or via a web-based application. Reports of potential compliance violations that we receive via our compliance hotline are reviewed by the Compliance Investigations and Case Management team.

Cases with a certain risk profile are presented to the Compliance Case Committee, which comprises senior representatives from our Compliance, Corporate Security, Data Privacy, Human Resources, Internal Auditing, and Legal departments. The Committee's duties include assessing and classifying certain compliance issues, investigating their background, and addressing these issues using appropriate measures.

Based on the investigation outcome and recommendations from the compliance investigation team or the Compliance Case Committee, appropriate disciplinary action may be taken against employees who have committed a compliance violation. If, during the investigation, a root cause is identified that could lead to the risk of further compliance violations, we take preventive and corrective actions.

The compliance hotline is also available to external stakeholders. The relevant information can be found in the Compliance and Ethics section of our [website](#).

The number of suspected compliance violations reported remained stable compared with the previous year, while the number of confirmed compliance violations decreased. In 2022, we received 79 compliance-related reports via the compliance hotline and other channels that were processed as cases. 28 violations of the Code of Conduct or other internal and external rules were confirmed.

Reported compliance violations

	2019	2020	2021	2022 Merck Group	2022 thereof: Merck KGaA
Total number of reported compliance violations					
Number of reported compliance incidents	75	81	79	79	3
Number of confirmed cases	30	41	42	28	0
Confirmed cases by category					
Bribery and corruption	9	6	1	2	0
Violation of cartel laws and fair competition rules	0	0	0	1	0
Fraudulent actions against Merck	8	11	6	11	0
Other violations of the Merck Compliance Principles for the relations with business partners	4	0	0	2	0
Other violations of Merck values, internal guidelines or legal requirements	9	24	35	12	0

Compliance audits

Compliance is ensured by Group Compliance and Group Internal Auditing as the second and third lines of defense. As part of the audits, Group Internal Auditing regularly reviews functions, processes and legal entities worldwide. These reviews include an assessment of the effectiveness of the respective compliance guidelines, processes and structures in place. The units also check for violations of our Code of Conduct and our Anti-Corruption Standard.

Our audit planning aims to provide comprehensive risk assurance through the best possible audit coverage of our processes. We take a risk-based approach to our annual audit planning process, considering factors such as sales, employee headcount, systematic stakeholder feedback and the Corruption Perceptions Index (**CPI**) published by the non-governmental organization **Transparency International**. If an internal audit gives rise to recommendations, Group Internal Auditing performs a systematic follow-up and monitors the implementation of the recommended corrective actions. In 2022, Group Internal Auditing conducted 79 internal audits involving bribery and corruption-related risks, including 52 operational and 24 IT audits and 3 special audits which may, for example, be initiated as part of incident-specific internal investigations.

Interactions with health systems

We support health systems by providing information to our healthcare stakeholders, such as professional medical associations, patient advocacy groups, university clinics and other institutions that provide healthcare. We follow clearly defined internal approval requirements and procedures for each type of interaction, in line with applicable laws and codes. In countries with statutory or industry obligations on the disclosure of transfers of value to healthcare stakeholders, we aim to comply with these obligations.

Direct-to-consumer advertising only in certain countries

Direct-to-consumer (DTC) advertising for prescription medicines is permitted in some countries, such as the United States. In line with applicable local laws, we use DTC advertising in these countries to help increase people's awareness of certain diseases and the available therapies.

Roles and responsibilities

For all interactions with healthcare stakeholders, we have established internal policies and review processes and tools, such as record-keeping systems, to ensure adherence to statutory requirements and transparency obligations.

Our Global Regulatory Affairs unit has established a dedicated standard and corresponding process document on the review and approval of our promotional materials for our Healthcare business sector. At the operational level, the relevant business and all employees involved in our sales and marketing activities must adhere to our internal policies, standards and procedures.

To ensure that all promotional materials meet our standards as well as local regulations end-to-end, we apply a harmonized Group-wide review and approval system.

Our commitment: Group-wide guidelines and industry standards

In addition to applicable laws and our own internal standards, we comply with the codes of conduct of various international and local industry organizations, such as the [Code of Practice](#) published by the International Federation of Pharmaceutical Manufacturers & Associations ([IFPMA](#)) and the Code of Practice of the European Federation of Pharmaceutical Industries and Associations ([EFPIA](#)) or the regulations of the U.S. Pharmaceutical Research and Manufacturers of America ([PhRMA](#)).

Moreover, we apply various specific internal rules and regulations:

- Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations (Pharma Code)
- Healthcare Ethical Guiding Principles
- Standard on Medical Activities
- Policy on Interactions with Patients, Patient Opinion Leaders, and Patient Organizations
- Guideline Good Practice and Process Guidance: Engagement with Patients, Patient Opinion Leaders, and Patient Organizations.

Transparent reporting

We publish the financial and non-financial contributions we make to healthcare stakeholders in the healthcare industry, such as healthcare professionals and healthcare organizations, as appropriate and in accordance with local laws and codes. The published information includes the names of individual recipients, their addresses, the purpose, and the contributed amount or value as required by the applicable laws and codes. In addition, before publishing, we secure all necessary informed consent forms, as required by the applicable data privacy regulations.

Regular employee training

We are continuing our Code of Conduct training curriculum on managing dilemmas in sector-specific situations. Employees who are responsible for the promotion of our pharmaceutical products receive regular training on current guidelines. Depending on their roles and responsibilities, new employees, participate in onboarding training dealing with the review and approval of promotional materials. Based on their roles and responsibilities and to remain up-to-date, employees participate in mandatory e-learning courses and classroom training on our policies and guidelines, as well as important changes to the reporting requirements for transfers of value.

Other topics

Sustainable innovation and technology

The sustainable innovation that we envision or drive forward must align with and support the three goals of our [sustainability strategy](#). We define sustainable innovation as new or improved products, services, technologies, or processes that generate economic benefits and have positive environmental and social impacts. Therefore, we develop long-term solutions for our innovation and research activities that consider the entire value chain and evaluate each product's impact over its lifecycle.

Today, our products already have a positive impact on human progress and global health, namely our medicines and our biological and chemical innovations that utilize the latest technologies. We want to continuously improve the way we measure our progress by adapting and integrating sustainability criteria into our product development processes across the business sectors.

In 2022, we continued our partnership with the well-established patent information platform LexisNexis® PatentSight®. In this context, we created a framework to evaluate the sustainability impact of our intellectual property. For 2022, we evaluated the baseline for the first time and identified that 27% of our patent families published that year have a positive sustainability impact based on LexisNexis® PatentSight®.

Roles and responsibilities

The organizational set-up of our R&D activities reflects the overall structure of our company. All three of our business sectors operate independent R&D units that pursue their own innovation strategies. Group Corporate Sustainability supports our business sectors and Group functions to advance and integrate sustainability within the R&D and innovation processes in line with our shared goals. We developed a methodology for creating a Group-wide overview of the potential contribution of our R&D portfolio towards sustainable solutions that went live in December 2022.

Our Group Science & Technology Office leads the implementation of our combined strategy for innovation, data and digital, enabling innovation across our business sectors while harnessing the power of advanced data and digital capacities. It aims to identify and integrate transformative, strategically relevant technology trends into our business sectors while maintaining a Group-wide view of our tech roadmap and innovation portfolio. Fostering data and digital capacities is key to accelerating sustainable innovation and enabling rapid action and personalized offerings. Innovation projects are incubated either through our corporate innovation teams or in the business sectors.

Our venture capital fund, [M Ventures](#), prioritizes sustainable innovations through equity investments. The fund's mandate is to invest in innovative technologies and products that have the potential to significantly impact our core business areas. In addition, the fund focuses on investments in two areas of high strategic relevance to our company: digital technology and sustainability.

M Ventures' sustainability investment strategy follows two fundamental approaches. First, it invests in sustainable solutions relevant to our three business sectors, such as novel solutions for reducing emissions and waste, green life science technologies and green electronics technologies. These solutions may be more energy- or resource-efficient or may create products designed for circularity or with a lower carbon footprint. The second approach involves making investments that leverage our core competencies to drive sustainability in other markets. These may include start-ups addressing sustainable foods, bio-manufacturing, or carbon capture and utilization.

Our commitment: Aiming for circularity

Within our R&D processes, we are committed to continuously improving and integrating sustainability and circular economy criteria to assess the sustainability performance of our products and portfolio. For example, our Life Science business sector developed Design for Sustainability (DfS) and the DOZN™ tool to create more sustainable products for our customers. In 2022, we tailored and rolled out the DfS concept to our two other business sectors and integrated an overarching company dashboard. In 2023, we aim to generate an understanding of our R&D portfolio and use the insights to steer future R&D activities. Therefore, we have developed an indicator to track our progress. In addition, we have dedicated corporate resources for our circular economy strategy and we are driving several circular economy pilots and initiatives throughout the organization.

Reporting in accordance with the EU Taxonomy Regulation

Fundamentals

The EU taxonomy for sustainable activities (hereinafter “EU Taxonomy”) is a classification system that translates the climate and environmental objectives of the European Union (EU) into criteria for sustainable economic activities. For this purpose, the EU Taxonomy defines various key performance indicators and qualitative information that Merck must disclose. The disclosure obligation under Article 8 of Regulation (EU) 2020/852 of the European Parliament and of the European Council dated June 18, 2020 on establishing a framework to facilitate sustainable investment and amending Regulation (EU) 2019/2088 (hereinafter “EU Taxonomy Regulation”) and the Delegated Acts adopted in this regard is being carried out in multiple phases:

- For the 2021 reporting period, key performance indicators were stated only for so-called taxonomy-eligible economic activities and were limited to those that make a substantial contribution to climate change mitigation or climate change adaptation as defined by the EU Taxonomy Regulation. An economic activity qualifies as taxonomy-eligible if it is within the scope of the EU Taxonomy.
- For the 2022 reporting period, apart from the degree of taxonomy-eligible economic activities making a substantial contribution to climate change mitigation or climate change adaptation within the meaning of the EU Taxonomy Regulation, it is also necessary to report the taxonomy-aligned share of the identified economic activities. According to the EU Taxonomy, an economic activity qualifies as taxonomy-aligned if it is taxonomy-eligible and makes a substantial contribution to one or more of the environmental objectives without doing significant harm to the other objectives or failing to fulfill minimum social standards.
- As of the 2023 reporting period, four further environmental objectives of the EU are likely to be included in the disclosure obligation: 1) sustainable use and protection of water and marine resources, 2) transition to a circular economy, 3) pollution prevention and control, and 4) protection and restoration of biodiversity and ecosystems.

Approach

To ensure the legally compliant fulfillment of its disclosure obligations, in 2020 Merck established an interdisciplinary project team that is continuously analyzing the existence of taxonomy-eligible and taxonomy-aligned activities in close coordination with the representatives of the business sectors and various Group functions.

The identification of the taxonomy-eligible economic activities for the environmental objectives “climate change mitigation” and “climate change adaptation” proceeded in line with a top-down approach using structured inquiries submitted to the relevant specialist departments. The results of this analysis were confirmed by supplementary big data-supported analyses as part of a bottom-up approach. Among other things, information was used that can also be found in connection with the requirements of the REACH regulation as well as in the context of customs declarations.

The three key performance indicators (KPIs), namely net sales, capital expenditure and operating expenditure, were mainly derived from existing financial reporting systems; for capital expenditure inquiries were made to the Investment Controlling unit in some instances.

Methodology for determining the taxonomy KPIs requiring publication

The EU Taxonomy Regulation and the corresponding Delegated Acts contain wording and requirements which, even taking into account the supplementary publications of the EU Commission and the “EU Platform on Sustainable Finance”, are subject to interpretation and for which clarifications have not yet been published in every case. The most significant interpretive issues arising in this context are presented below.

Taxonomy-eligible economic activities of Merck

To check the taxonomy eligibility of an economic activity, Merck applies an end-product oriented approach for manufacturing-related activities. This means that the end product must result from one of the economic activities specified in the Delegated Act in order to qualify as being taxonomy-eligible. In the case of organic basic chemicals, the corresponding economic activities only qualify as taxonomy-eligible in the interpretation of Merck if the manufacturing activities of the named chemical products involve a significant transformation process. In our interpretation, products that are merely passed on for sale, repackaged or mixed do not qualify as taxonomy-eligible within the meaning of the EU Taxonomy Regulation.

In the course of implementing the EU Taxonomy requirements, the business model of Merck underwent a comprehensive analysis. The core business activities of Merck are not mentioned in the economic activities set forth by the Delegated Act. Consequently, taxonomy-eligible activities were only identified to a very small extent in conjunction with the production of energy-efficient building equipment in the Electronics business sector. By contrast, neither the manufacture nor the distribution of pharmaceutical products or the distribution of specialty chemicals, which form the core of the business activities of the Life Science and Electronics business sectors, qualify as application areas of the EU Taxonomy Regulation for the first two environmental objectives. Furthermore, ancillary activities that are operationally necessary for our core business also do not qualify as independent taxonomy-eligible economic activities. This applies, for example, to the acquisition or construction of production buildings, the transport of our products to our customers as well as to research and development activities that cannot be allocated to a taxonomy-eligible economic activity for the first two environmental objectives “climate change mitigation” and “climate change adaptation”.

With respect to capital expenditure, the EU Taxonomy Regulation differentiates between three categories of capital expenditure:

- Capital expenditure that relates to assets or processes associated with taxonomy-aligned economic activities (Category A),
- Capital expenditure that is part of a plan to expand taxonomy-aligned economic activities or to transform taxonomy-eligible economic activities into taxonomy-aligned economic activities (Category B), and
- Capital expenditure related to the acquisition of products from taxonomy-eligible economic activities and individual measures that carry out the target activities in a low-carbon manner or reduce greenhouse gas emissions (Category C).

Because Merck only engages in taxonomy-eligible economic activities in the area of manufacturing energy-efficient building equipment to a very small extent owing to its business model, it has no significant capital expenditure in category A. Furthermore, Merck has no capital expenditure in category B since it does not prepare any capital spending plans to transform the taxonomy-eligible economic activities for the first two environmental objectives “climate change mitigation” and “climate change adaptation” into taxonomy-aligned economic activities. This is attributable to the fact that there are hardly any taxonomy-eligible activities due to the business model of the Group.

Consequently, Merck only has capital expenditure for the first two environmental objectives resulting from the acquisition of products classified as taxonomy-eligible economic activities or are attributable to qualifying individual measures (Category C). In order to be taxonomy-eligible, this capital expenditure must correspond to one of the economic activities named in the Delegated Acts and be implemented and operational within 18 months. At Merck, such capital expenditure exists especially in connection with

- transport by motorbikes, passenger cars and light commercial vehicles (activity 6.5)
- construction and real estate (activities 7.2 to 7.7).

In order to exclude double counting, capital spending on products from taxonomy-aligned economic activities and individual measures that have already been checked under category A are only included under category A. Against this background, capital expenditure for production buildings, for example, is only subject to a taxonomy-eligibility check under category A, while capital expenditure for administrative buildings is included under category C.

Taxonomy alignment of the economic activities of Merck

In order to check the taxonomy alignment of the taxonomy-eligible economic activities, the relevant regulations for the technical screening criteria under which certain economic activities qualify as contributing substantially to the environmental objective as well as for determining whether the activity causes no significant harm to any of the other environmental objectives were systematically analyzed. The basis for this was the Delegated Acts on the EU Taxonomy, which were used for the identification of taxonomy-eligible economic activities. In these, corresponding requirements are defined for the respective economic activities, which must be fulfilled for a classification as taxonomy-aligned. For this purpose, interviews were conducted with business and project managers and physical climate risk analyses were carried out at the sites. Furthermore, operating permits, product data sheets, environmental product declarations, energy performance certificates and internal training documents were inspected, among other things.

Minimum safeguards

The minimum protection frameworks include the OECD Guidelines for Multinational Enterprises, the United Nations Guiding Principles on Business and Human Rights, the fundamental conventions of the International Labour Organization, and the International Bill of Human Rights. The requirements profile of the frameworks was systematized and compared with internal documents. This included an analysis of the Code of Conduct, work instructions, guidelines and training documents. Compliance with the due diligence process required by the framework in the area of human rights is ensured with respect to the individual business activities. Risk analyses are carried out with regard to the minimum protection requirements and appropriate measures are derived from these.

Taxonomy KPIs

Net sales

The KPI net sales represents the ratio of net sales from taxonomy-eligible or taxonomy-aligned economic activities in a fiscal year to the total net sales of the same fiscal year. The definition of relevant net sales for the purposes of the EU Taxonomy Regulation corresponds to the definition of net sales in the consolidated financial statements (see Note (9) "[Net sales](#)" in the Notes to the Consolidated Financial Statements).

Capital expenditure

The share of capital expenditure on assets or processes associated with economic activities classified as taxonomy-eligible or taxonomy-aligned is determined as follows: Share of total capital expenditure that is taxonomy-eligible or taxonomy-aligned divided by total capital expenditure according to the EU Taxonomy Regulation. At Merck and within the meaning of the EU Taxonomy Regulation, capital expenditure in the

reporting period comprises additions to property, plant and equipment (IAS 16), rights of use from leases (IFRS 16), and intangible assets (IAS 38) with the exception of goodwill. Apart from the additions, advance payments for the named assets are also included. The denominator also includes additions to property, plant and equipment and intangible assets resulting from business combinations. The additions can be seen in the changes in property, plant and equipment and intangible assets disclosed in the consolidated financial statements (see Note (20) "[Property, Plant and Equipment](#)" and Note (19) "[Other Intangible Assets](#)" in the Notes to the Consolidated Financial Statements)

Operating expenditure

The share of operating expenditure for assets or processes associated with economic activities classified as taxonomy-eligible or taxonomy-aligned is determined as follows: Share of total operating expenditure that is taxonomy-eligible or taxonomy-aligned divided by total operating expenditure according to the EU Taxonomy Regulation. Operating expenditure relevant within the scope of reporting under the EU Taxonomy Regulation includes direct, non-capitalized research and development costs, low-value leases, building renovations, maintenance and repair, and all other direct internal and external expenses related to the day-to-day maintenance of property, plant and equipment that are necessary to ensure the continuous and effective functioning of these assets.

Fossil gas-related activities

Merck operates a gas turbine and a co-generation unit to generate electricity and heat from fossil gaseous fuels. The unit serves to generate our own power and heat. The activities in the area of electricity generation from fossil gaseous fuels as well as the operation of co-generation units with fossil gaseous fuels are not significant at Merck. Additional activities in the field of nuclear energy and fossil gas are not performed.

The following tables present the share of sales, capital expenditure and operating expenditure attributable to taxonomy-eligible and taxonomy-aligned economic activities in respect of the environmental objective “climate change mitigation”.

[illegible]

[illegible]

[illegible]

The low share of taxonomy-eligible net sales, capital expenditure and operating expenditure in connection with the environmental objective “climate change mitigation” is mainly due to the very limited conformity of the business activities of Merck with the economic activities set forth in the EU Taxonomy Regulation.

Research and development expenses accounted for € 2,521 million (2021: 2,426 million) of the reported operating expenditure, with € 1,694 million (2021: € 1,712 million) of this being attributable to the Healthcare business sector.

No additional taxonomy-eligible and taxonomy-aligned net sales, capital expenditure or operating expenditure were identified for the environmental objective “climate change adaptation”.

Outlook

For the environmental objective “pollution prevention and control,” which is likely to be disclosed for the first time for the 2023 reporting period, Merck expects a higher share of taxonomy-eligible economic activities than for the objectives “climate change mitigation” and “climate change adaptation”, which are already subject to the reporting requirement. This assessment is based on proposals for technical screening criteria by the “Technical Working Group of the EU Platform on Sustainable Finance”, which, with respect to the environmental objective “pollution prevention and control”, list to a vast extent the production of chemicals, pharmaceutical and chemical products, and pharmaceutical products as taxonomy-eligible economic activities. These proposals will flow into the development of the Delegated Act through which the European Commission will define the technical screening criteria. As regards the degree of taxonomy alignment of the relevant economic activities for the environmental objective “pollution prevention and control”, a reliable estimate is not possible at the present time due to the uncertain legal situation.