Vigilance Plan

GRI Standards:

2-25: Processes to remediate negative impacts
2-26: Mechanisms for seeking advice and raising concerns
2-27: Compliance with laws and regulations
308-1, 308-2: Supplier Environmental Assessment
407-1: Freedom of Association and Collective Bargaining
408-1: Child labor
412-1, 412-2, 412-3: Human Rights Assessment
414-1, 414-2, 414-3: Supplier social assessment
418-1: Customer Privacy

EXECUTIVE SUMMARY

This document meets the requirements of the French law on the duty of vigilance of parent and ordering companies of March 27, 2017.

It aims to present the measures of the Company's vigilance plan, based on Sanofi's various approaches to HSE, human rights, product safety and responsible purchasing.

It also aims to report on the progress of these different approaches.

The vigialnce plan covers Sanofi's activities, those of its globally integrated companies, and the activities of tier-one suppliers and subcontractors.

TABLE OF CONTENTS

1. Contexte

Law No. 2017-399 of March 27, 2017 on the duty of vigilance of parent and ordering companies, known as the duty of vigilance law, introduces a duty of vigilance into the Commercial Code for parent companies of groups that employ at least 5,000 employees in France or 10,000 employees worldwide. This duty of vigilance consists of establishing, effectively implementing and publishing "reasonable vigilance measures to identify risks and prevent serious violations of human rights and fundamental freedoms, the health and safety of individuals and the environment". These measures must concern the activities of subsidiaries, subcontractors and suppliers with whom there is an established business relationship.

They must be formalized in a Vigilance Plan that is made public and included in the company's management report, as well as a report on its effective implementation. Vigilance measures include risk mapping, value chain assessment procedures, mitigation and prevention actions, alert mechanisms and monitoring of the effective implementation of measures.

The purpose of this document is to present the measures of the Company's vigilance plan, based on Sanofi's various approaches to HSE, human rights, product safety and responsible purchasing. It also aims to report on the progress of these different approaches ("*implementation report*").

The vigilance plan covers Sanofi's activities, those of its fully consolidated companies, as well as the activities of Tier 1 suppliers and subcontractors.

1.1. GOVERNANCE AND STEERING OF THE VIGILANCE PLAN

Our vigilance approach is under the joint control of our heads of CSR and HSE. Global coordination is provided by our CSR department, who ensure that there is a good fit between the various measures in the vigilance approach, and that those measures are implemented.

The CSR department works closely with our HSE, Procurement, Legal Affairs and Ethics & Business Integrity departments; its remit includes global oversight of Vigilance Plan implementation. Monitoring of risk management policies and whistle-blowing systems is the responsibility of the specific departments concerned, such as HSE.

1.2. DIALOGUE WITH STAKEHOLDERS

Sanofi makes regular presentations to trade unions about the rollout and monitoring of the Vigilance Plan, via a working group mandated by the Group Works Council. Meetings are held to discuss issues, such as risk mapping relating to human rights at work, sustainable procurement, whistle-blowing, and supplier assessments.

One meeting was held in January 2023, during which the issues presented included a follow-up on internal control points relating to policies on human rights at work; progress in procurement; and a status update on whistle-blowing reports under the duty of vigilance.

1.3. GRIEVANCE MECHANISM

Since 2006, a whistleblowing system has been in place to allow any employee to report any breach of the Code of Ethics. A secure line is available 24/7 with a dedicated web page. A toll-free number is available in 28 languages. In the United States, a hotline, guaranteeing independence and anonymity, has been set up for Sanofi employees, in accordance with local regulations and practices.

The hotline allows an employee who encounters a problem or who believes in good faith that a law, regulation, a provision of the industry code of conduct, a Sanofi policy or standard, or one of the principles set forth in the Sanofi Code of Conduct has been or is about to be violated, to report it by the means he or she deems most appropriate.

Employees will not be disciplined or discriminated against because of reporting to the whistleblowing system, provided that they act in good faith, without intent to injure, even if the facts prove to be inaccurate or no further action is taken.

Sanofi employees are encouraged to identify themselves when reporting an incident, as this helps the investigation process. However, if they prefer not to disclose their identity, they can report anonymously. The system is also open to third parties interacting with Sanofi. Each report, whether received through the whistle-blowing system or through any other channel, is investigated internally using a methodological protocol set out in our whistle-blowing policy. If an internal investigation confirms the allegations, corrective and/or disciplinary measures are taken. To ensure that such measures are determined consistently and uniformly, Sanofi has issued a policy formally documenting an overall framework for corrective and/or disciplinary actions. This policy was updated in 2022, reinforcing a culture of integrity and respect, zero-tolerance behaviors (fraud, harassment, discrimination), organizational justice and speaking up.

In 2022 the E&BI department received 565 alerts. A total of 238 cases were substantiated and resulted in 88 dismissals or resignations related to misconduct. Other corrective actions were also implemented as per Sanofi's disciplinary and corrective actions policy, for example: additional training, process improvement steps, remuneration impacts, and verbal or written warnings.

In addition to this global ethical alert system, specific mechanisms for collecting alerts and reports on drug safety are available to patients. These mechanisms depend on the different countries of activity.

Examples:

France United-Kingdom India

2. *Identification of vigilance issues*

2.1. METHODOLOGY FOR IDENTIFICATION AND PRIORITIZATION

For the purposes of the vigilance plan, Sanofi considers that the only risks to be considered are those relating to impacts on people and the environment.

For risks specific to the duty of vigilance, we apply a three-step methodology:

(1) identify major issues inherent to the sector in which we operate;

(2) classify and evaluate, at business unit and support function level, the criticality of the risks associated with each major issue; and

(3) evaluate the level of control over these risks and prepare action plans to manage them.

In determining major risks to people or the environment, we applied a sector-based approach to identify which of our stakeholders are potentially affected and our major vigilance issues. For this, we drew largely upon feedback on our existing policies and internal processes, and in particular: the "Human Rights in Our Activities" guide, which identifies key human rights issues over the life cycle of our products; our approach, reinforced in 2017, of identifying the highest-risk categories of purchases and hence of suppliers; this involves allocating each category a score in terms of inherent risk (to human rights, health and safety, and the environment), and then weighting that score to reflect country risk..

Based on this analysis, backed up by external data - sourced from industry initiatives, such as Together for Sustainability (TfS) and Pharma Supply Chain Initiative (PSCI), international research studies and a peer

benchmarking exercise - we were able to identify **salient vigilance issues relating to the protection of patients, our employees, the environment, and local communities**. These vigilance issues are related to Sanofi's activities, whether we carry out those activities ourselves or through our direct commercial relationships.

For each issue identified, we assessed our existing risk management actions against criteria, such as the existence and implementation of a policy (from definition of the commitments underpinning the policy, through to controls over its application) or of a company-wide action plan. Based on this assessment of the level of control, we were able to rank the residual risk and establish adequate action plans.

2.2. SALIENT ISSUES IDENTIFIED

Category	Risk	Description
Health and safety	**Employee health and safety***	Risk that we may fail to provide a safe work environment and cause harm to our employees, suppliers or subcontractors, with immediate or future consequences for their health.
	Product safety for patients and consumers*	Risk of product safety breaches, from first administration in clinical trials on humans through to the end of the product's life cycle, that could have an adverse effect on patients or healthcare professionals.
Human rights and fundamental liberties	**Patient safety in clinical trials***	Risk that we will breach ethical standards (informed consent, transparency of results), which could have an adverse effect on patient safety.
	Biopiracy*	Risk that we will fail to respect state sovereignty or the intellectual property rights of indigenous peoples when obtaining patents and commercializing endemic resources identified as a result of bio-prospecting traditional practices and know-how.
	Personal data protection*	Risk that we will fail to respect the privacy of customers, employees, patients or healthcare professionals by compromising the integrity, confidentiality or accessibility of their personal data.
	Fundamental human rights at work*	Risk that the fundamental human rights of employees will be breached as a result of our operations, or those of our suppliers or subcontractors.
Environment	**Minimize water consumption***	Risk that we will withdraw too much water relative to the capacity of the ecosystem and the needs of other users, especially the most vulnerable.
	Minimize environmental discharges*	Risk that discharges and emissions from our industrial and R&D operations will adversely affect the environment or human health or will not be appropriately managed by our own staff or by our suppliers or subcontractors.

**Indicates risks that apply not only to our own operations, but also to those of our suppliers, subcontractors, and partners. See section 8.*

3. Protection of patients

3.1. PRODUCT SAFETY FOR PATIENTS AND CONSUMERS

Sanofi develops, manufactures and sells a vast portfolio of healthcare solutions around the globe, from prescription medicines and consumer health products to vaccines and medical devices. We are obliged to meet legal and regulatory requirements on the safety of products through their entire life cycle, from research to end use, and also aim to:

- protect patient health by monitoring the safety of our medicines and constantly assessing the benefit/risk profile of our products;

- supply physicians, healthcare professionals and patients with full and up-to-date safety information, including potential risks associated with a product;
- report to the regulatory authorities on a timely basis, in accordance with international and local regulatory requirements and our own Global Quality standards; and
- set up a dedicated and holistic approach to fight against falsified medicine and illicit trafficking, to protect patients and preserve trust in the supply chain

3.1.1. Organization

The Chief Safety Officer (CSO) is responsible for our Global Pharmacovigilance (GPV) organization; this is supervised by our Chief Medical Officer (CMO)/Global Head of Development, who in turn reports to Sanofi's Global Head of R&D. This governance model ensures that information flows directly and rapidly to Sanofi's decision-making bodies, especially in the event of a potential or actual public health crisis.

GPV is Sanofi's center of excellence for assessing and monitoring the safety and benefit/risk profile of the full spectrum of Sanofi products, except the Consumer Healthcare portfolio (see below).

All pharmacovigilance activities relating to the use of the product portfolio report to GPV. Staff from GPV deploy their specialist expertise at all stages of the product life cycle, from pre-development to the end of the commercialization cycle.

To meet the expectations of the supervisory authorities, patients and healthcare professionals, GPV has specialist scientific and medical teams for each therapeutic range. These multi-disciplinary teams prepare the supporting evidence needed for monitoring the benefit/risk ratio and for identifying and assessing potential signals, and for implementing risk minimization measures. This pragmatic, evidence-based approach to the benefit/risk ratio protects patients and consumers in an ethical, scientifically sound and transparent way. GPV also has a team of pharmaco-epidemiologists, tasked with establishing the methods and /or scientific rationale to be applied in evaluating the efficacy, risk, benefit and use of our medicines in real-life situations over large populations or patient groups, or via specialist databases.

A pharmacovigilance signal (or safety signal) is a hypothesis of a possible risk between taking a medicine and an adverse event, derived from data from one or more of many possible sources. In practice, a safety signal occurs when a parameter (such as the number, incidence or frequency of an adverse event) deviates from what is expected or accepted. This hypothetical deviation then needs to be analyzed, so it can be confirmed or rejected.

To maintain the safety of our Consumer Healthcare (CHC) Portfolio, a dedicated Pharmacovigilance organization has been established, which went live in January 2022. The Head of the Consumer Safety & Evidence team reports to the Science Hub Officer, who in turn reports to the Executive Vice President Head of CHC. This organizational setup ensures rapid information exchange and full managerial oversight. At the same time, efficient and effective collaboration with all other scientific functions is assured by embedding the Pharmacovigilance organization in the Science Hub.

The CHC Pharmacovigilance organization is organized into three main functions: the Therapeutic Area (covering Signal Management aspects), Risk Management, and PV Science. The QPPV Office oversees PV activities, including Quality and Compliance as well as Training activities. The PV Operations team maintains our Pharmacovigilance tools and is in charge of periodic Safety Reports.

3.1.2. Policy and action plans

GPV proactively monitors national and international regulations and recommendations. A centralized regulatory watch unit within GPV analyzes changes in pharmacovigilance legislation in real time, so that we can always adapt our work processes to align on the latest requirements and good practices. GPV draws upon a worldwide network of local and regional managers trained in pharmacovigilance. GPV provides a range of services to this network; these include allocating sufficient resources and budgets to fulfil our mission; monitoring good practices; maintaining regulatory compliance; training; and access to the tools needed for the network to discharge its responsibilities in accordance with quality standards.

Sanofi systematically aligns on the most exacting standards of Good Pharmacovigilance Practices.

We also have a dedicated quality system and dedicated compliance teams in place, to ensure that all our pharmacovigilance activities comply with official regulations.

Sanofi holds memberships in well-established international initiatives such as scientific consortia, international pharmaceutical industry associations, and professional networks working on predictive pharmacovigilance scenarios.

Pharmacovigilance is a constantly changing field, whether scientifically and medically or in terms of data processing. To ensure that as a responsible pharmaceutical company we continue to apply best practice in the changing landscape, GPV is constantly improving its governance structure. We have identified the following strategic areas as having the highest priority:

- capitalizing on human capital and strengthening our medical capabilities by rolling out an individualized skillset development model. In 2022, we regularly added to our skillset directory so that our pharmacovigilance staff are up to speed with the latest regulatory and scientific practices, and qualified to meet future needs; and
- integrating digital strategies by delivering an ambitious technological development plan to automate and apply artificial intelligence to the processing of our pharmacovigilance data. This was seen as a pre-requisite not only for managing the growing volume of data but also for addressing the diversity of sources of safety information, including social media and patient support programs.

  The ramp-up of our new technological platform shows evidence of delivering business value and quality, with highly satisfactory key performance indicators in line with initial expectations. For GPV, 2023 will be a milestone year in the full global implementation of the pharmacovigilance tech platform. The rollout will be accompanied by a transparent, proactive communication policy towards regulatory bodies at key steps in the process. The platform will leverage artificial intelligence and automation to support safety experts in their assessments by:

- deploying a structured approach to benefit/risk profile evaluations, relying if necessary on population-based epidemiological statistics; and
- integrating real-life and epidemiological data in our strategies for detecting and evaluating potential signals associated with the use of Sanofi products.

In parallel with these pharmacovigilance-oriented improvements, from an organizational perspective, GPV has continued on the Sanofi Transformation Journey:

- extending its scope of expertise and onboarding new competencies:
  - in the growing field of acquisitions and divestments, and portfolio management (e.g. the CHC carve-in, Principia, Translate Bio, Kiadis, Kadmon, etc.); and
  - creating a translational safety center of expertise. This innovative approach relates to clinical and nonclinical safety assessments used to support drug discovery and development, and encompasses the steps that must be taken to translate nonclinical safety findings into predictions of adverse outcomes in humans); and
  - creating the conditions to simplify our PV organization in selected geographies and countries by identifying partners capable of ensuring sustainable distribution of our portfolio of medicines and vaccines for patients.

One of Sanofi CHC's key objectives in 2022 has been to set up and maintain a Pharmacovigilance system that complies with all internal and external requirements and is best adapted to CHC's specific portfolio, consisting mainly of medicinal products, medical devices, food supplements and cosmetic products. Over the course of 2022, Sanofi CHC Pharmacovigilance continued to use the Sanofi PV tools and systems and followed all system related PV processes, in particular those related to case management, signal management, risk management, periodic safety reporting and literature searches. CHC is subject to internal audits, and one Health Authority PV inspection was successfully concluded in 2022.

In 2023 further activities will be initiated aiming to increase the level of autonomy of CHC PV through establishing dedicated digital PV tools and revising processes and ways of working. A key aspect of this transformation will be the migration of CHC PV data into a dedicated Pharmacovigilance database.

3.2. PERFORMANCE INDICATORS

Signals assessed	2022	2021	2020
Total signals	333	375	344
Of which PRAC/HA signals [a][b]	126	188	125

(a) PRAC = Pharmacovigilance Risk Assessment Committee of the European Medicines Agency; HA = Health Authorities.

(b) The difference between total safety signals and PRAC/HA signals represents signals derived from the Sanofi Pharmacovigilance database.

Pharmacovigilance audits and inspections	2022	2021	2020
Number of audits	37	41	33
Number of inspections	4	4	5

These audits and inspections are included in the figures reported in the Product quality section ("4.3.3.3., Performance indicators").

Our performance indicator of submissions of individual pharmacovigilance cases to the European healthcare authorities by the regulatory deadline reached 98.9% in 2022.

Performance indicators for Consumer Healthcare are included in the above values.

3.3. PATIENT SAFETY IN CLINICAL TRIALS

Clinical trials are a mandatory part of the approval process for any new healthcare solution. Their purpose is to collect data about the efficacy and safety of products in healthy subjects and patients, so that the benefit/risk profile can be evaluated. Sanofi organizes clinical trials all over the world. Clinical trials may also be carried out post-marketing approval to develop new indications for a drug or monitor its safety.

Sanofi applies international standards: the Declaration of Helsinki, the recommendations of the International Council for Harmonization (ICH), and in particular Good Clinical Practices (GCP). In addition to these international standards, Sanofi complies with all national and international rules and laws applicable to clinical trials, including European Directives 2001/20/EC (on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, published in Official Journal L 121 of May 1, 2001, page 34, as amended in 2006 and 2009) and 2005/28/EC (laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products, published in Official Journal L 91 of April 9, 2005, pages 13-19); the CFR21 regulations issued by the US Food and Drug Administration (FDA); and the regulations issued by the Japanese Ministry of Health, Labor and Welfare (MHLW).

We conduct clinical trials in lower-income and middle-income countries in certain very specific circumstances, applying the same quality and ethical standards as we do in higher-income countries (see also section 4.3.2, "Access to healthcare"). In particular, our Sanofi Pasteur vaccines business conducts trials of the pediatric hexavalent vaccine SHAN6, which was specifically developed for such countries. We also participate in the Clinical Research in Resource-Limited Settings working group of the Council for International Organizations of Medical Sciences (CIOMS), which issued its final report in June 2021.

Sanofi ensures that all participants enrolled in clinical trials (or their legal representatives) give their free and informed consent. Consent must be given before any procedure or intervention required by the study protocol is carried out on a participant, and before any data are collected. All documents related to clinical trials, in particular the consent form, must comply with applicable legislation and must provide participants with exhaustive, easily understandable information. To simplify the consent form supplied to participants and reflect recent major changes in the ethical landscape (especially in terms of informed consent), our teams use an internal reference document that is subject to regular review; the latest version was issued in 2022.

Sanofi has for many years implemented an internal audit program covering clinical trials, associated systems and any subcontractors involved in the conduct of trials. The aim is to obtain assurance that the conduct of trials complies with our quality standards and the applicable regulations, and to continually improve our practices. Our audit program is designed to cover clinical trials of which Sanofi is the sponsor, in various countries and regions around the world. We also perform regular audits of subcontractors retained to improve clinical trial performance.

Finally, we are subject to inspections by health authorities to ensure that we are complying with ethical standards and legislation.

Performance indicators

None of the 55 inspections conducted on our clinical research activities in 2022 resulted in regulatory action.

After a decrease of approximately 50% in regulatory inspections from 2020 linked to the COVID-19 pandemic (which also called for a number of adaptations to enable electronic sharing of data and documents), the number of inspections began to rise again in 2022, though without returning fully to pre-pandemic levels.

4. Employee health and safety

4.1. SANOFI HSE POLICY

As a global healthcare player, we are committed to providing a safe and healthy workplace for all employees and contractors working at our sites, while minimizing the environmental footprint of our activities and products. To deliver on this commitment, Sanofi has developed an HSE strategy based on a management system that is consistent with the issues faced by the company in its activities and involves the whole organization. The policy is established by our HSE department, validated by our senior management, and signed off by our CEO.

A cornerstone of the Sanofi HSE strategy, this policy is integral to our commitment to corporate social responsibility.:

- we constantly strive to embed an HSE culture where each person takes responsibility for preventing accidents and harm to health, promoting wellness at work, and reducing environmental impacts. This message is shared with everyone in Sanofi;
- development projects and product launches are assessed for potential risks to health, safety and the environment. These assessments draw on all our scientific and technical knowledge, use the best technologies available, and take account of the life cycle of the product in question;
- to protect the environment, we pay close attention to the impacts of our operations and products by conserving water and energy, and reducing the impact of emissions, effluent and waste across all our industrial, R&D and commercial activities. We are also actively engaged in fighting climate change; and

- we encourage our suppliers, co-contractors and subcontractors to apply our HSE rules; when assessing and referencing them, we use application of our HSE rules as a criterion.

We adopt a constructive approach to transparency and dialogue with third parties on our HSE policy.

Sanofi drew upon the resources of its in-house HSE network to coordinate the response to the COVID-19 pandemic. A global crisis unit was set up at the onset of the crisis, along with similar units in each country, to coordinate the preparation and management of our response. Weekly meetings were held in each country throughout the crisis to ensure that procedures were being properly applied.

As a healthcare company, we set out strict safety measures to protect all our people against the pandemic, including barrier measures, temperature control and managing COVID-19 cases. We established decision-making tools and criteria for tightening or easing lockdown, driven by the data in each country. Through a dedicated website and a range of other support measures, we helped our people adapt to new ways of working. These included tips on staying physically fit, on dealing with the mental health pressures of working from home over extended periods and being socially isolated, and on how to achieve good ergonomic conditions.

4.2. ORGANIZATION

In deploying the Sanofi HSE strategy, our global HSE organization is based on three pillars, all under the direction of our Global Head of HSE, who in turn reports to a member of our Executive Committee. Global HSE covers all business segments and geographies, and the entire life cycle of Sanofi products, and comprises:

- a global center of excellence, using scientific and technical expertise to develop global strategies across the whole of Sanofi, and providing support to our operations and partners;
- HSE Business Partners for our R&D and Industrial Affairs activities, subsidiaries and sales forces, tasked with cascading the global strategies down within their sphere of operations and monitoring performance; and
- regional HSE managers who provide operational support aligned on global and business-specific strategies and on local regulations.

The global HSE function is backed up by:

- a dedicated HSE department within each of our industrial, research and tertiary sites, representing around 700 employees in total across 45 countries who run and implement HSE programs at site level;
- professional firefighters at sites where this is required (such as those classified as "Seveso" because of hazardous substances); and
- occupational health services, either in-house or outsourced, offering medical coverage appropriate to the nature of occupational risks. Internationally, the HSE department has a leadership team of eight Key Medical Doctors (KMDs), based in the regions of the world where we operate, who develop and harmonize occupational risk prevention and medical surveillance activities within Sanofi in compliance with local regulations.

Finally, our HSE department heads up a number of expert committees that assess the impacts and hazards of substances and biological agents.

4.3. MANAGING HSE RISKS

Our HSE department has established a risk evaluation methodology that is applied to all our sites and is consistent with Sanofi's global risk evaluation methodology. The aim of this risk mapping process is to obtain a comprehensive overview, from site level upwards, of the criticality of the principal HSE risks to which Sanofi is exposed and the level of control over those risks.

Each site carries out a comprehensive risk evaluation program covering all its activities once a year or whenever a significant change occurs, which is signed off by management at site and activity level. The

evaluation methodology identifies and quantifies hazards and assesses the level of risk in light of the extent to which the risk is controlled and the nature of the site:

- evaluation of regulatory compliance, including environmental permits, operating licenses, management of hazardous chemicals, transport of hazardous goods, and any regulated substances on the site;
- evaluation of the risk of exposure in occupational health terms, including potential exposure to chemicals, biosafety hazards and radiation, physical stress factors, noise, vibrations, and ergonomic issues;
- evaluation of major risks affecting business continuity, including process safety, risks of explosion or fire, and exposure to natural risks;
- evaluation of workplace risks, including solitary work, road safety, asphyxia, hazardous machinery, the risk of working at heights, handling and lifting equipment, electricity, and managing hazardous work sites; and
- evaluation of environmental risks, such as soil pollution, waste management, water and effluent management, atmospheric emissions and climate change.

A global HSE Risks Committee consolidates the site-level risk mapping and draws up a company-wide HSE risk map, which is then sent to Sanofi Risk Management.

All risk maps are translated into action plans which are periodically monitored at site level.

Each site establishes and maintains its own emergency response plan, adapted to reflect site-specific risks and the internal or external resources that would be deployed, or called upon, in response to those risks.

Special case: sites with "Seveso" classification (major risks)

Our chemical manufacturing sites in Aramon and Sisteron in France are classified as "Seveso III" (from the name of the European directive relating to potentially hazardous sites, providing a list of activities and substances and the associated classification thresholds). In accordance with French law on technological risk prevention, the Aramon and Sisteron sites are subject to more stringent safety inspections due to the toxic or flammable materials stored on the sites and used in their operating processes.

The two European sites classified as "Seveso III" establishments have specialized response resources, implemented by standby crews and employees who have received second response training.

4.4. HSE MANAGEMENT SYSTEM

Sanofi distributes an HSE policy reference manual to all sites.

The manual sets out measures to be applied so that activities can be managed in a way that minimizes risks and impacts. It describes Sanofi's standards and methodological tools and builds in the results of risk/opportunity analysis and expectations on the part of stakeholders – including customers, NGOs, investors and civil society.

Seeking to improve at all times, the HSE department management has set out our HSE 2025 ambitions in a roadmap, backed by quantified objectives and action plans, that is shared across all levels of Sanofi.

Each site is subject to periodic monitoring to assess adherence to action plans and attainment of objectives.

The entire management system is reviewed regularly.

4.5. HSE COMPLIANCE AND INTERNAL AUDITS

Wherever we do business, we are committed to complying with the HSE laws and regulations that apply to us and to implementing recommendations made by external audits conducted (for example) by our insurers, customers, or standards bodies.

In addition to the regulatory watch role carried out by our global experts within their sphere of competence, individual sites also monitor local HSE regulations and compliance with local administrative and HSE requirements.

The HSE department runs audit programs to assess compliance with internal HSE rules and standards.

These audits are carried out by Sanofi Lead Auditors who are registered with the International Register of Certified Auditors (IRCA), supported by other staff members who have recognized HSE experience and have followed a dedicated training program accredited by IRCA. In advance of the periodic HSE audits, an independent expert conducts a compliance audit to check that local regulations are being applied. The HSE audit then checks that this was conducted properly and that an action plan is in place to deal with any non-compliance.

	2022	2021
Number of internal HSE audits, including Biosafety	36	50
Number of auditors with IRCA accreditation	18	17
Number of employees who have performed audits	51	71

In 2022, ten of our sites were accredited to ISO 45001 standards.

In addition to our own internal verification and audit procedures, our sites are also subject to regular inspections by local authorities, or to regulatory inspections by third parties on specific issues. For example, 100 visits were made during 2022 by technical experts from our insurers.

4.6. WORKPLACE HEALTH AND SAFETY PROGRAMS

4.6.1. Occupational injury prevention

Preventive measures are designed primarily to reduce the number and severity of occupational injuries and to minimize the exposure of permanent and temporary Sanofi employees, as well as our subcontractors.

Sanofi has implemented a sophisticated real-time monitoring tool that alerts management as soon as possible after an accident has occurred, and tracks frequency rates. A monthly report is issued to operational managers and a quarterly report is sent to the Chief Executive Officer and the Executive Committee members.

Analysis of occupational injuries includes a review of the root causes of serious and potentially serious accidents; identification of noncompliant situations and near misses; safety visits; and sharing of good practice. This helps guide the implementation of specific local or global preventive programs involving technical, organizational and people-based measures. The Sanofi “Safety Culture” program urges all employees to take an active interest in their own safety, and that of their colleagues, by raising their awareness of the hazards and risks in their day-to-day environment and in their tasks, actions and practices.

Learning from experience (incidents and good practices) is based on a dedicated reporting datasheet containing an analysis of significant incidents, the immediate and root causes, and actions to be taken (some of which, if the issue is serious enough, will have to be completed within a specified timeframe). The datasheets are prepared by experts and disseminated through the entire HSE network, and to operational and site managers (R&D, industrial and administrative). A total of 23 HSE Vigilance and Best Practices datasheets were distributed in 2022 to the whole global HSE network.

Preventive measures are also taken at site level, based on their risk analyses and actual incidents.

4.6.2. Road safety

After two years in which COVID-19 and lockdowns significantly reduced time spent in the field, our medical representatives took to the road again in 2022 to meet healthcare professionals. The total distance traveled in 2022 was 18.8% higher than the previous year.

Hands-on training cycles largely replaced and supplemented the online sessions introduced during recent years. This year, a large-scale campaign called "One Hour Stop For Safety" was once again run in the vast

majority of countries where we operate. This sees employees taking an hour out of their work routine so they can get together and discuss road safety risks and how to drive more safely.

In 2022, we revamped the format of road safety training delivered by line managers, making it simpler and more impactful. An international working group devised a new approach which encourages drivers to identify how they can improve their driving, and sets up action plans which are then followed up in a second session.

4.6.3. Occupational health

Based on an evaluation of health risks, each site implements risk prevention programs and occupational health practices in accordance with Sanofi's HSE rules. This mainly involves individual and collective containment and protection measures to prevent exposure at all workstations where chemical substances or biological agents are handled.

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continually assess the effects of products on human health, especially that of our employees. These assessments form part of the work of two committees, covering chemical risks (COVALIS) and biological risks (TRIBIO), which determine adequate preventive and protective measures for our people. These committees pool the resources of our network of international experts and draw upon Sanofi standards and policies.

In addition, specific resources are allocated to the implementation of the European Union regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). In compliance with the European CLP regulation on the classification, labeling and packaging of chemical substances, we have registered the relevant substances with the European Chemicals Agency (ECHA).

All personnel are monitored under medical surveillance programs that are based on the results of occupational risk assessments linked to their duties.

Occupational diseases and their causes are divided into categories based on international standards. For the purposes of prevention, the number and cause of occupational diseases is consolidated for Sanofi as a whole on an annual basis. This improves data reporting and gives a better understanding based on local regulations that may vary greatly from country to country.

In line with European statistics, the principal type of occupational disease reported and recognized within Sanofi during 2022 in accordance with local administrative criteria was the musculoskeletal disorder category.

4.6.4.Health and safety training

We invest in training and awareness programs designed to embed the prevention of health and safety risks into everything we do.

Each new employee receives initial health and safety training appropriate for their job profile so that they can perform their work in strict compliance with the rules. Depending on their jobs, employees may then follow other training modules specifically related to what they do.

Founded in 2012, the Sanofi HSE Academy enables all employees to access the training programs developed and approved by our HSE department, supplementing the training provided directly by local sites.

Our training offer is a mix of periodic courses and specific training to address new needs and challenges facing Sanofi.

Highlights of 2022 include:

- We launched new pilot programs accessible worldwide to improve understanding of HSE issues around product stewardship and develop HSE leadership skills, plus the "SAFETY 2.0" program for our senior manager community. For France-based staff in strictly admin roles, we rolled out a new "Riskopoly" e-learning module to improve safety culture.
- Alongside these new initiatives, we continued delivering our periodic training courses, such as the "HAZOP" operational safety risk analysis program (nearly 70 trainees); "Onboarding for HSE

- Managers" (around 40 trainees); "Managerial Safety Visit Coaching" (nearly 50 employees certified); and the "Auditor Pool" course, which enabled us to add 18 new auditors to our existing audit teams.
- We also continue to work on translating existing e-learning modules, to make them more accessible and broaden their reach. A good example is the "Planet Care" program, which is now available in eight languages.

4.6.5. Occupational injury/disease indicators

TOPIC	AMBITION	PROGRESS		CONTRIBUTION TO SDGs
		2022	2021	
Health and safety in the workplace	Reduce the total occupational injury frequency rate (any employee) below 2 by 2022	2.0	2.0	**SDG 8**: Decent work and economic growth **SDG 8.8:** Protect labor rights and promote safe and secure working environments for all workers, including migrant workers, in particular women migrants and those in precarious employment.
	Reduce the lost time injury frequency rate – any employee below 1.4 by 2022	1.3	1.3	

(a) "Any employee" includes Sanofi employees, temporary workers and subcontractors.

	2022	2021
Lost time injury frequency rate[a] – Sanofi personnel	1.1	1.0
Lost time injury frequency rate[a] – Contractors	2.2	2.1
Total occupational injury frequency rate – Sanofi personnel	1.6	1.6
Total occupational injury frequency rate – Contractors	3.3	3.1
Number of deaths	1	0
Number of occupational diseases reported[b]	19.0	30.0

(a) Number of lost-time accidents of one day or more per million hours worked over a 12-month period.hours worked. For sedentary employees, accidents occurring on the way to and from work are not included in this indicator. However, they are recorded for traveling sales representatives, in accordance with the reporting rules defined by Sanofi.

(b) In 2021, Sanofi opted to consolidate data based on the reporting rate, so as to avoid adjusting prior-period data.

In 2022, Sanofi unfortunately recorded a fatal accident at an industrial facility in France. An action plan and global communication plan were instigated immediately, and a working group set up to strengthen the company's safety culture; this will be deployed in 2023.

31% of accidents were due primarily to ground-level falls and contact with objects. However, the ground-level falls prevention program initiated in 2018 has had a positive impact, with the number of accidents of this type well below the 2018 level (127 in 2022, 207 in 2018).

A total of 19 occupational diseases were reported to local authorities in 2022, compared with 30 in 2021. The main reduction was in musculoskeletal disorders, which also accounted for the majority of occupational diseases: 10 in 2022 (53%), and 23 in 2021 (77%).

A total of 14 occupational diseases were reported in Europe (France), three in the United States, and two in Canada, where systems for identifying and reporting such diseases are well established.

We also used an additional medical reporting system (Mood), which showed a resurgence in mental health issues that may be partly due to the effect of the pandemic on our people's working lives.

To remedy this situation, worldwide guidelines on workplace wellness (including mental health) were rolled out in 2022.

5. Fundamental human rights at work

We employ more than 91,000 people in many countries and work with a large number of suppliers and subcontractors. This gives us a duty to respect the human rights of workers both in our own operations and in our supply chain. Fundamental human rights at work refer mainly to rights associated with ILO standards (International Labour Organization), and in particular the following conventions:

- freedom of association and recognition of the right to collective bargaining (ILO conventions 87 and 98);
- elimination of all forms of forced labor (ILO conventions 29 and 105);
- effective elimination of child labor (ILO conventions 138 and 182);
- elimination of discrimination in employment (ILO conventions 100 and 111);
- wages and employee benefits (ILO conventions 95, 131 and 135); and
- weekly rest (ILO conventions 14 and 106).

Sanofi has committed to applying international standards on human rights, including the United Nations Guiding Principles on Business and Human Rights, and to carrying on its activities in compliance with national regulations such as the French Duty of Vigilance law.

To do this, we identify the nature and extent of potential human rights violations in every country in which we, our suppliers and direct subcontractors operate, and take action to prevent any breach of the rules or of our own internal policies.

A description of our risk mapping, organization, policies, action plans and performance monitoring in respect of human rights is provided below.

5.1. HUMAN RIGHTS RISK MAPPING

The following risks have been specifically identified as salient for Sanofi as regards the fundamental rights of employees:

1) for sales, R&D and support function activities: psychosocial risks, and the risk of isolated practices that may be prejudicial to freedom of association and the principle of non-discrimination; and

2) for manufacturing and logistics activities: risk of employing migrant workers in situations that may be tantamount to forced labor; risk of excessive working hours; risk of wages below decent wage levels; risk of hazardous work being carried out by children aged under 18; and the impossibility for Sanofi to meet its commitments on freedom of association and non-discrimination in at-risk countries.

The risk factors we use to identify and evaluate the criticality of human rights risks are related to the characteristics of the labor force used (level of qualification, working conditions, potential presence of

vulnerable workers) and of countries where we do business (such as legislation that is inadequate or contrary to international standards, widespread human rights violations, or a large presence of vulnerable populations in the country). Because we classify our employees by what they do (industrial, sales, support functions, etc.), we were able for each risk to determine its probability and severity (the seriousness of the potential risk and the number of people potentially affected, and whether the potential violation is systemic or isolated). This methodology was developed in consultation with our Risk Management department.

5.2. ORGANIZATION

Sanofi has for many years adopted a proactive vigilance approach to prevent our activities having negative impacts on human rights. Three of our support functions play key roles in this approach. Our CSR department provides expertise in embedding human rights into our activities; our HR function implements policies and action plans; and the Internal Control and Internal Audit functions check that the policies are being implemented and complied with.

5.3. POLICIES AND ACTION PLANS

We pay particular attention to respect for the fundamental rights of employees, whether employed directly by Sanofi or indirectly by parties with whom we do business. In 2015, we approved and rolled out three internal policies on freedom of association, prohibition of forced labor and prohibition of child labor. These policies reiterate our commitments to employees and establish processes to translate those commitments at operational level by identifying and controlling the risk of infringements of these rights and requiring the implementation of due diligence. Our policies are based on ILO conventions, and in particular on:

- ILO Conventions 87 and 98 on freedom of association, protection of the right to organize and collective bargaining;
- ILO Conventions 138 and 182 on child labor; and
- ILO Conventions 29 and 105 on forced labor.

To ensure that these policies are properly implemented, specific control points have been built into our internal control system, covering respect for freedom of association and the right to collective bargaining; the elimination of all forms of forced labor; and the abolition of child labor.

We strengthened our existing processes in 2018:

- we updated our "Human and Labor Rights" risk profile to improve the way in which we rank human rights risk (which we define as the risk of violating the human rights of workers) and how we assess severity in terms of the seriousness of the impacts on employees; and
- we classified risks relating to the fundamental rights of workers and ranked them by criticality (see section 4.3.6.1., "Risk mapping"), and revised our existing policies to make risk assessment questionnaires compulsory and more operational, and to ensure that data are reported up to the CSR department.

5.4. PERFORMANCE INDICATORS

In 2019, we refined our human rights risk mapping so as to identify those countries where we need to focus our internal audit efforts. We identified 18 at-risk countries based on the following criteria: level of country risk, number of employees, and presence of production or distribution activities. These countries represent approximately one-third of the Sanofi workforce. Of these 18 countries, nine (representing more than a quarter of the Sanofi workforce) have already been subject to audit.

In 2022, 16 countries (Algeria, Brazil, China, Colombia, Egypt, India, Indonesia, Mexico, Pakistan, Russia, Saudi Arabia, South Africa, Thailand, Turkey and Vietnam) responded to the internal control questionnaire. The main findings are summarized below:

Issue	Findings
Child labor	No major compliance breaches reported No employment of persons under the age of 18 Systematic verification of age upon hiring
Main control points:	
- No hiring of children aged under 15, or aged under 18 for dangerous work	
- Verification of age on hiring	
- Danger level assessment of jobs for young workers/compliance with ILO working hours	
Forced Labor	No major compliance breaches reported Written and transparent employment contracts Regular salary payments No withholding of wages or recruitment fees at the end of the contract. Means to alert on wage issues without fear of reprisals No overuse of temporary workers No overreliance use of overtime Difficulties reported by some countries relating to issues around decent wages
Main control points:	
Existence of written, transparent employment contracts	
- Regularity of wage payments	
- Transparency and clarity of calculation methods, payslips, etc.	
- No need to work overtime to earn a decent wage	
- No withholding of wages or recruitment costs (including by recruitment agencies	
- No retention of identity papers	
Working hours	Compliance with 48h/week and daily working hours, weekly rest day and two weeks paid vacation Some issues on overtime due to discrepancies between the global standard and local legislation
Main control points:	
- Compliance with ILO working hours standards: weekly, daily, overtime, paid leave, maternity leave.	
Freedom of association	Reports of difficulties applying standards due to local legislation in certain countries
Main control points:	
- No discrimination based on trade union membership, and no abusive practices against worker representatives.	
- Respect for the right to collective bargaining	

Corrective action plans are being drawn up within the entities concerned, on top of collective actions taken at company-wide level (see above).

Furthermore, two countries (Brazil and India) were audited by an independent third party on their self assessment questionnaires answers and no findings were identified.

6. Personal data protection

For Sanofi, it is essential that we protect the personal data of our employees and of patients, healthcare professionals and other partners with whom we interact. This is especially important in light of current developments in information and communication technologies.

6.1. ORGANIZATION

Our Data Protection Officer is responsible for implementing a Privacy and Personal Data Protection program within Sanofi. In this, he is supported by our corporate privacy team (the Global Privacy Office), and an international network of Local Privacy Officers (LPOs) in each country where we have subsidiaries. He is also supported by a network of Functional Privacy Officers (FPOs), representing global functions such as

Research & Development, People & Culture, Information Technology & Solutions, Finance, Commercial Services, Manufacturing & Supply, and our Global Business Units. In 2022, the Global Privacy Office became part of our Global Ethics & Business Integrity (E&BI) function, so as to emphasize the importance of using personal data ethically and responsibly within our privacy protection strategy.

6.2. POLICIES AND ACTION PLANS

Our global approach to the processing of personal data is set out in two documents: the Sanofi Global External Privacy and Data Protection Policy, and the Sanofi Global Internal Privacy and Data Protection Policy. Both policies are worldwide in scope and apply to all Sanofi employees processing personal data. The commitments set out in the policies are without prejudice to the application of and compliance with the privacy laws and/or local culture of each country where we process personal data.

We also apply our policy requirements contractually to third parties processing personal data on behalf of Sanofi (such as consultants, service providers, vendors or other partners), for example by asking them to sign data transfer agreements.

The very nature of our business requires the processing of data of individuals who receive our treatments. Such data may be collected in clinical trials or genetic and epidemiological studies, during the monitoring of pharmacovigilance information, and under Patient Support Programs. No consent is required for the reporting of adverse events for pharmacovigilance purposes, but the person reporting the signal - usually a healthcare professional - will inform the patient that their health data is being transferred but that it will not be directly identifiable. Such data transfers are for pharmacovigilance purposes only, and are restricted to the holder of the marketing approval and to health authorities responsible for pharmacovigilance.

The Global Privacy Office is now rolling out a new application, OneTrust, to replace PRIMA. Like PRIMA, OneTrust helps users to check that projects involving the processing of personal data comply with regulations and Sanofi policy, to determine any corrective action required, and to update the Sanofi data processing register. This ensures there is an audit trail for all such projects. OneTrust offers additional functionalities including managing security incidents affecting personal data; bringing websites that use cookies into compliance; managing requests from people whose data are held and who wish to exercise their rights; and mapping IT systems and service providers involved in the processing of personal data.

The Global Privacy Office also continues to develop and distribute awareness-raising videos and training modules so that all our employees know the importance of issues around the protection and transfer of data within Sanofi. Finally, the Global Privacy Office has issued a set of Position Papers and a Privacy Checklist to support project managers as they implement a Privacy-ByDesign culture.

7. Protect environment and communities

7.1. MINIMIZE THE USE OF WATER RESOURCE

7.1.1. Water resource managment plan

Water is a key component in our industrial operations. We need it to keep our factories running, and it is an integral part of the manufacturing process for medicines.

Water is used directly in chemical and pharmaceutical production, whether as an ingredient at the synthesis or formulation stage or to clean equipment and networks between production cycles. In both cases, a range of water treatment processes are in place at each site to guarantee a very high degree of purity prior to use.

Utility services (steam, process water and cooling systems) are the biggest users of water at Sanofi. Water is primarily used as a vector for calorific transfer (cooling and heating) in the manufacturing processes for our products, from chemical synthesis to vaccine manufacture.

We seek to use this resource responsibly and sustainably, by implementing water management plans at all of our industrial sites. The aim is that all our sites will have such a plan by 2030, and that those with a high level of water-related risks (especially those in water stress zones) will have one by 2025.

This year, Sanofi again completed the Water Security questionnaire of the Carbon Disclosure Project (CDP), obtaining an Arating, confirming our position in the "leadership band". This result recognizes our achievement in consistently reducing the water footprint of our industrial operations over several years.

There are many water-related risks, but they can be classed in three main categories: physical, regulatory and reputational. In 2020, we launched a large-scale campaign to update water risk mapping across all our industrial sites, with the help of an external consultant. This program helped to update the list of priority sites in early 2021. Since the EUROPA spin-off, this list has been reduced from 12 to 10 priority sites, located in Algeria (two), India (three), Mexico (two), South Africa (one), China (one), and Saudi Arabia (one).

7.1.2. Water consumption

Water used directly and indirectly during manufacturing is essentially withdrawn directly by Sanofi itself from underground or surface bodies of water. We have specific operating procedures for effectively managing our use of water, and for reducing our consumption through moderation and recycling.

We reviewed our water program in 2021 in order to improve our response to current and future challenges. Water is a local resource, so it is for each site to determine the priority issues in their catchment; that's why our water management plans incorporate context-driven targets. At global level, we define our target for reducing water withdrawal by aggregating our local targets (rather than vice versa); after all, France does not face the same challenges as India.

We have estimated that implementing our sustainable water management program will reduce our global water withdrawals by 15% by 2030 versus the 2019 baseline, despite the ongoing development of our industrial capacities.

Water consumption (millions of m3 per year)	**2022**	**2021**	**2019 (baseline year)**	**Change vs 2019 (%)**
Withdrawal of surface water (lakes, rivers)	1.8	1.6	2.5	-29%
Withdrawal of groundwater	1.7	1.8	2.4	-28%
Withdrawal of water from public supply	5.9	6.1	6.0	-2%
Other sources	2.2	2.2	2.4	9%
TOTAL	11.6	11.7	13.4	-13%

7.2. BIOPIRACY

Sanofi is committed to complying with conventions on the protection of biodiversity and combating biopiracy. Compliance with local regulations derived from the Nagoya Protocol requires coordinated efforts across all Sanofi entities. In 2017, we put in place appropriate documentation and policies relating to the Nagoya Protocol. We also created a dedicated intranet site, accessible to all our employees, to raise awareness of the Nagoya Protocol. Staff in key departments receive regular training. To continue the internal rollout and ensure compliance, we set up a Nagoya expert group, who report to our Bioethics Committee. The Nagoya expert group continues to work on issues arising from implementation of the protocol in the signatory states. The aim is to monitor how practices are changing in light of the reaction from stakeholders. For example, the use of digital sequence information on genetic resources is an issue still under review. The actions taken by Sanofi relate to the use of natural substances to develop new medicines.

These include abiding by the principle that when we commercialize products derived from natural substances, we share our profits with countries that allow access to their natural resources and with local populations who have specific know-how. So whenever we investigate the use for R&D purposes of a new

product isolated from a natural source, we will carry out due diligence to ensure we comply with international conventions.

The COVID-19 pandemic has highlighted the difficulties around including human pathogens in the scope of the Nagoya Protocol, and reignited the debate at international level.[1]

7.3. MINIMIZE RELEASES TO THE ENVIRONMENT

Our R&D and manufacturing operations - and the storage and transportation of raw materials, products and waste - are associated with various potential risks relating to the release of toxic chemicals or biological pathogens that may adversely affect the environment or human health. We have implemented a range of action plans to limit these impacts, ensure that we comply with regulations and our own internal directives, and anticipate the impact of new and emerging regulations relating to the release of contaminants into the environment in every country where we operate. We are also working on impacts that occur after patients have used our products.

7.3.1. Organization

As the Environment Department is part of the HSE Department, the organization related to the environment is presented in the "Employee Health and Safety" section.

7.3.2. Policies and action plans

7.3.2.1. Managing pharmaceutical contamination and combatting bioresistance

Pharmaceutical substances may be found in the environment as a result of medicines taken by patients and then excreted; inappropriate disposal of unused or date-expired medicines; and effluent from manufacturing sites. We strive to prevent and reduce the environmental impact of pharmaceutical substances (including antibiotics) by taking actions across the entire life cycle of our products, from development and manufacturing to end-of-life post patient use.

Our key actions are:

- evaluating and reducing the potential environmental impacts of our production sites, through a global program with a particular focus on the discharge of pharmaceutical substances in effluents;
- obtaining new data to improve our understanding of how medicines impact on the environment, and assessing the environmental risks associated with patient use;
- promoting proper use of our medicines. This involves awareness campaigns directed at healthcare professionals and/or patients. Using medicines properly not only improves patient health, it also helps the environment: correct diagnosis, prescription and dispensing, followed by good therapeutic observation and proper disposal of unused medicines, all reduce the impact of waste medicines on the environment; and
- encouraging responsible disposal of unused or date-expired medicines, by raising patient awareness and supporting collection programs.

We also signed up to the Anti-Microbial Resistance (AMR) to help combat microbial resistance to antibiotics. This initiative initially brought together 13 major players in the pharmaceutical industry to collaboratively produce guidance and reference frameworks for the sustainable management of antibiotics within the industry. It includes a specific commitment relating to antibiotics manufacturing sites operated by signatories and their suppliers, involving the definition and implementation of a common framework for managing potential discharges and the setting of shared environmental limits.

[1] https://www.ifpma.org/subtopics/public-health-implications-of-the-implementation-of-the-nagoya-protocol/

7.3.2.2. Managing other types of wastewater discharge

Directly related to our policy on managing pharmaceutical substances in the environment is our commitment to managing wastewater discharge. We have various programs in place for:

- monitoring trends in the concentration of pollutants in the natural environment;
- reducing the quantities discharged at source; and
- installing state-of-the-art or innovative treatment facilities at sites, where necessary.

Wastewater generated by our operations is always treated before being discharged into the natural environment, either directly using our own installations or indirectly under agreements with municipal or industrial partners to use their treatment facilities.

Our own in-house treatment plants are subject to a rolling program of maintenance, monitoring, reporting and performance optimization. This includes equipment upgrades, and improvements to flow management, such as treatment at source, flow segregation and dedicated treatment processes.

Onsite HSE teams are responsible for checking that our discharges comply with all relevant licenses and agreements. They are also tasked with implementing environmental and public health impact assessment programs. These programs involve:

- profiling flows of pollutants (sources, quantities and composition);
- pollution management strategies (reduction at source, segregation, outsourcing, and dedicated or centralized treatment facilities); and
- monitoring discharges and auditing the performance of treatment facilities.

7.3.2.3. Managing air emissions: optimizing the use of solvents and control over volatile organic compound emissions

Solvents (primarily used in the production of active ingredients, and in their transformation into pharmaceutical products) are governed by company-wide recommendations on their use.

Solvents used in the production process are either purchased (consumed quantities) or regenerated on site. We encourage process optimization, regeneration (when possible) and waste-to-energy technology in an effort to reduce consumption.

Controlling volatile organic compound (VOC) emissions from drug synthesis and manufacturing activities is a priority for Sanofi. An integrated approach is applied at each stage of product development, from research to production, aimed at:

- avoiding the use of solvents by substituting biological processes for chemical processes;
- encouraging the recycling of solvents;
- selecting the least toxic solvents;
- reducing emissions at source through specific adjustments to manufacturing processes and maximum containment of solvent use; and
- capturing and treating residual VOC emissions at special treatment facilities using the best available techniques for the specific physicochemical properties of the VOCs emitted (cryogenic capture, gas scrubbers, thermal oxidizers, activated carbon).

7.3.3. Performance indicators

Significant events with an environmental or regulatory impact are systematically reported at global level.

7.3.3.1. Managing releases of pharmaceuticals into the environment

Since 2016, we have been gradually rolling out a program to evaluate and reduce the environmental impact of potential releases of pharmaceutical substances from our manufacturing sites. At site level, this translates into dedicated discharge management plans that include a profile of discharges and emissions, the application of environmental thresholds, and the implementation of any risk management measures that may be necessary. At the end of 2022, this program covered 72% of our chemical synthesis and

dosage form sites, and 100% of our priority sites (which are identified on the basis of a risk analysis by substance and by site).

We are proactively assessing the environmental impact of the active ingredients in the products we sell, starting with our strategic products. Our efforts in this field are being supported by research partnerships with various stakeholders, including universities and other manufacturers. In 2022, we revisited our prioritization process, and complied a list of our top 100 marketed products (by sales and unit volumes sold). To date, our evaluation program has already covered 66% of those substances.

The performance of our suppliers and subcontractors is monitored closely as part of our supplier audit approach (see "Procurement and Subcontracting").

We also support unused medicine collection schemes (like the Cyclamed scheme in France) in many countries. Finally, we conduct awareness campaigns to help patients use medicines properly, especially antibiotics.

7.3.3.2. Managing other types of wastewater discharge

Chemical oxygen demand (COD) is the most relevant parameter for assessing the quality of wastewater discharges, since it measures the overall quantity of organic material (biodegradable and non-biodegradable) in the wastewater.

Most of our industrial facilities have wastewater treatment plants, whether or not the wastewater is discharged directly to the natural environment. If discharge is to a public or private sewerage system, then treatment is handled by a third party who complies with locally applicable regulations.

Consequently, the overall quantity of COD calculated within our site boundaries (rather than at the point of discharge into the natural environment, as reported in previous years) would appear to be a more reliable and relevant indicator of our efforts to reduce the environmental impacts of our operations on aquatic ecosystems.

Wastewater discharge *(tonnes)*	**2022**	**2021**	**2019 (baseline year)**	**Change vs 2019 (%)**
COD	4,243	4,499	4,711	-10%

The many programs under way to upgrade our onsite treatment plants, and the embedding of new environmental criteria into the design of our facilities, suggest that levels will stabilize in the years ahead despite the ongoing expansion of our industrial capacities.

The quantity of COD generated by our sites accounts for most of the footprint from our chemical and biochemical production; it is low compared to many other industries, especially since the spin-off of EUROAPI. The overall reduction in COD discharges mainly reflects lower intensity of production at those facilities, as a result of modernization or other events affecting how production is organized.

7.3.3.3. Managing air emissions: optimizing the use of solvents and control over volatile organic compound emissions

Solvents (Tonnes)	**2022**	**2021**	**2019 (baseline year)**	**Change vs 2019 (%)**
Solvents used	90,178	86,911	89,354	+1%
Percentage of regenerated solvents	57%	53%	57%	0%

Volatile organic compounds (VOCs) (tonnes)	**2022**	**2021**	**2019 (baseline year)**	**Change vs 2019 (%)**
VOCs (estimated)	1,399	1,429	1,320	+6%
SO_x – direct emissions	55	110	203	-73%

NO_x (Tonnes)	**2022**	**2021**	**2019 (baseline year)**	**Change vs 2019 (%)**
NO_x – direct emissions	361	369	414	-13%

We adopt a proactive approach to monitoring and testing and have invested heavily in new techniques to improve thermal oxidation efficiency. We adopt a proactive approach to monitoring and testing, and have invested heavily in new techniques to improve thermal

oxidation efficiency. The sharp fall in Sox emissions was due to a significant reduction in heavy fuel oil consumption and switch to natural gas at a facility in India, and an overall cut in natural gas consumption.

7.3.4. Remediation

7.3.4.1. Programs and resources devoted to preventing environmental risks and pollution

In accordance with our own HSE policy and regulatory requirements, all our sites are equipped with containment systems and/or systems for collecting accidental releases to prevent them from penetrating the soil.

We also have a systematic multi-year soil and groundwater monitoring and evaluation program for our sites, both for those with ongoing operations and those being sold. Where necessary, remediation work is carried out following detailed evaluations.

Capital and operating expenditures incurred on preventing environmental risks and contamination form part of the overall expenditures incurred on the implementation of Sanofi's HSE policy.

Environmental fines imposed on Sanofi in 2022 were immaterial.

7.3.4.2. Provisions and guarantees for environmental risks

Applicable environmental laws and regulations may require Sanofi to eliminate or reduce the effects of chemical substance discharge at our various sites. The sites in question may belong to Sanofi, and may be currently operational, or may have been owned or operational in the past. In this regard, Sanofi may be held liable for the costs of removal or remediation of hazardous substances on, under or in the sites concerned, or on sites where waste from activities has been stored, without regard to whether the owner or operator knew of or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred the discharge of those substances was authorized.

As is the case for a number of companies in the pharmaceutical, chemical and agrochemical industries, soil and groundwater contamination has occurred at some of our sites in the past and may still occur or be

discovered at others. In Sanofi's case, such sites are mainly located in the United States, Germany, France, Hungary, Italy and the United Kingdom. As part of a program of environmental surveys conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Sanofi sites. In cooperation with national and local authorities, Sanofi regularly assesses the rehabilitation work required and carries out such work when appropriate. Long-term rehabilitation work is in progress or planned at Mount Pleasant and Portland in the United States; Frankfurt in Germany; Brindisi in Italy; Dagenham in the United Kingdom; Ujpest in Hungary; Beaucaire, Valernes, Limay, Neuville and Vitry in France; and at a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi.

We may also have potential liability for investigation and cleanup at several other sites. We have established provisions for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. In France specifically, we have provided the financial guarantees for environmental protection required under French regulations.

Potential environmental contingencies arising from certain business divestitures are described in Note D.22.d to our consolidated financial statements, included at Item 18 of our 2020 Annual Report on Form 20-F. In 2022, Sanofi spent €39 million on rehabilitating sites previously contaminated by soil or groundwater pollution.

Due to changes in environmental regulations governing site remediation, our provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques involved, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations arising from the past involvement of Aventis in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision.

We have established, in accordance with our current knowledge and projections, provisions for cases already identified and to cover contractual guarantees for environmental liabilities relating to sites that have been divested. In accordance with Sanofi standards, a comprehensive review is carried out once a year on the legacy of environmental pollution. In light of data collected during this review, we adjusted our provisions to €526 million as of December 31, 2022, compared with €650 million in 2021. The terms of certain business divestitures, and the environmental obligations and retained environmental liabilities relating thereto, are described in Note D.22. to our consolidated financial statements, included at Item 18 of our 2022 Annual Report on Form 20-F.

8. Vigilance regarding the practices of suppliers and subcontractors

We buy raw materials, goods and services all round the world, and use a diversified panel of suppliers reflecting the diversity of our activities. Our Procurement function is centralized and acts in the name of all Sanofi entities (including our Global Business Units and support functions).

This structure delivers synergies in terms of both expertise and procurement costs. Our procurement policy, which applies to all our employees, is based not only on economic principles but also on ethical, environmental and social principles.

Procurement key figures	2022	2021	2020
Procurement spend (€ billion)	17.8	14.1	14.8
in OECD countries	16.2	12.7	13.3
in non-OECD countries	1.7	1.4	1.5
Number of suppliers	43,680	52,563	54,507

Number of countries where we have suppliers	132	128	138

Through responsible sourcing, Sanofi aims to minimize risks and create stable, long-term business relationships with selected partners who are screened through a risk-based approach.

For procurement categories considered at risk from a sustainability standpoint, suppliers are either audited (most critical vendors), or subject to thorough due diligence questionnaires.

Supplier audits, focusing primarily on Health, Safety and Environment (HSE) performance, but also, when relevant on Human Rights issues, are conducted by the Sanofi HSE department or outsourced to external auditors. These supplier audits are mainly targeted at high-risk subcontractors manufacturing critical Sanofi raw materials. Action plans are continuously monitored to ensure issues are remedied.

Due diligence questionnaires are managed through a third-party provider. The detailed questionnaire assesses supplier maturity for a wide range of CSR criteria.

On labor and human rights, Sanofi suppliers are required to comply as a minimum least with international human rights treaties, without prejudice to more favorable national laws. In particular, compliance with ILO (International Labor Organization) fundamental conventions by suppliers is an essential requirement for Sanofi. The following aspects are scrutinized in Sanofi's procurement process: child labor, working hours, wages and fringe benefits, and freedom of association.

8.1.1.Supplier Code of Conduct

Sanofi’s commitment to responsible procurement is reflected in our Supplier Code of Conduct, with which any supplier – and any

supplier of our suppliers – must comply. They are expected to respect:

- labor regulations against child labor, forced labor, violence, and discrimination (International Labor Organization, ILO core conventions);
- decent working conditions (working hours, wages and benefits, freedom of association);
- health and safety: workers’ health and safety protection, hazard information and training, and emergency preparedness; and
- environment: regulatory compliance, climate change mitigation, minimizing releases in the environment (air, water, soil),
- pollution prevention, reduction of energy and water usage, and biodiversity.

The Supplier Code of Conduct is integrated into our electronic ordering systems. Each time a supplier is onboarded, they must acknowledge and agree to our Supplier Code of Conduct, which is available in the Document Center on www.sanofi.com.

8.1.2.Supplier Risk Assessment

Our procurement risk approach encompasses all procurement categories and assesses macro risks (geopolitical, economic, technological, legal, natural disasters); operational risks, such as supply (single source, dependency); financial and strategic business issues; compliance risks, such as fraud and business ethics issues; and sustainability risks, including environmental, social and governance issues.

Sustainability risks are assessed through our 267 procurement sub-categories. The categories are assessed based on their inherent risk in terms of health and safety, the environment and human rights, each of which is scored from 1 to 4. Inherent risk is determined regardless of the country of operation, as follows:

- health and safety: number of people potentially affected, and seriousness and irreversibility of the consequences on people;
- environment: extent of the negative consequences (in terms of pollution and use of natural resources) on the environment, communities and biodiversity (whether or not limited to the site), and their irreversibility; and

- human rights: the characteristics of the workforce (level of qualification, number, temporary or permanent), and awareness of human rights issues around the products used.

As a result of this compound rating, 47 procurement categories are considered at risk from a sustainability standpoint. The underlying purchases are mostly related to the following activities and products: Capex, Energy, Packaging, Consumables, Waste Management, Active Ingredients, Raw Materials, Subcontracting, Clinical Trials, Transport and Distribution.

Suppliers belonging to these 47 categories are monitored depending on their sub-classification:

- Group A: Audits; and
- Group B: Third-party assessment

	2022	2021	2020
Number of suppliers assessed on their CSR performance	273	392	237
Number of assessed suppliers that met our CSR requirement	237	315	172
Percentage of assessed suppliers that met our CSR requirement	87%	80%	72%
Number of buyers trained to use the Responsible Procurement Platform [(a)]	447	389	70

(a) cumulative

Sanofi assessed 273 suppliers in 2022. Of those, 234 were undergoing a reassessment and 67% of those had improved their rating after following an action plan.

8.1.3.Supplier Selection

Since 2022, suppliers participating in Sanofi tenders have had to go through a compulsory sustainability assessment, encompassing social responsibility, environmental policies, CO2 emissions and product/service traceability. This assessment contributes to up to 20% of a supplier's score card in the tender award process. If a supplier does not have measures against forced labor, child labor and discrimination, it cannot be selected.

If not already in place, suppliers need to commit to go through a third-party assessment (all purchases); measure their Scope 1 & 2 CO2 emissions (goods purchases); have plans to measure Scope 3 and disclose their CDP climate assessment (goods purchases); and apply a robust Diversity, Equity and Inclusion policy (service purchases).

If a supplier is selected and has a sustainability score below average, corrective action plans need to be integrated into the contract and implemented within one year.

8.1.4.Supplier Onboarding

As part of their onboarding process, suppliers considered at risk from a sustainability standpoint as per the supplier risk assessment are systematically requested to complete a third-party assessment. This is carried out through a dedicated supplier onboarding platform, which by the end of 2022 covered 84 of the 91 countries where we carry out procurement. This solution also manages other targeted due diligence (anti-bribery, financial and cybersecurity), and the systematic sign-up of our vendors to our Supplier Code of Conduct.

8.1.5.Supplier Evaluation

Sustainability evaluations are managed through a third party. In line with its CSR ambitions, the scope of suppliers to be assessed represents 700+ suppliers:

- top 300 suppliers by amount of spend – mandatory;
- high-risk suppliers (approx. 400) – mandatory (as defined in section 8.1.2.); and
- suppliers participating in Sanofi tenders (as defined in section 8.1.3.).

Our objective is to carry out around 300 supplier assessments per year, the aim being to achieve the coverage of all our strategic high-risk suppliers by 2023. We currently stand at around 50%.

The assessment must be renewed at least every three years, and suppliers with a score below target must implement corrective action plans in areas flagged as insufficient. In the event of significant and/or non-remediated deviations, Procurement may decide to conduct on-site audits or terminate the relationship.

8.1.6.Supplier Audits

Supplier audits, focusing primarily on Health, Safety and Environment (HSE) performance, but also, when relevant, on Human Rights issues, are conducted by Sanofi's HSE Department or outsourced to external auditors. In 2022, our objective was to have carried out audits of all our critical high risk active pharmaceutical ingredient (API) providers and contract manufacturing providers, which has been achieved. The plan was risk phased:

- 2017-2020: focus on all antibiotics and hormones providers; and
- 2020-2022: focus on feedstock (synthesis intermediates) providers.

From now on, we will re-focus on critical and antibiotics suppliers to drive improved performance (see below).

	2022	2021	2020
Number of Sanofi CMO audits[(a)]	46	60	42
Number of audits of active pharmaceutical ingredient (API) suppliers[(a)]	81	88	44
Number of audits of other suppliers: packaging, logistics, CROs (Contract Research Organizations), etc. [(a)]	43	24	35

(a) Includes shared PSCI audits.

Improvement plans are monitored through re-assessments or follow-up audits:

	2022	2021	2020	2019
Number of active suppliers audited (cumulative)	757	667	573	427
Number of suppliers audited during the year with critical findings	8*	38	45	103
For suppliers audited with critical findings:				
Number of supplier relationships terminated	2	14	19	30

Number of suppliers who have improved	4	9	36
Number of suppliers subject to re-audit	20	18	37

*Data YTD October 2022.

8.1.7.Cross-sectoral Initiatives

Since 2017, Sanofi has been a member of the Pharmaceutical Supply Chain Initiative (PSCI), a grouping of 72 pharmaceutical and healthcare companies who share a vision of better, social, environmental, and economic outcomes for their suppliers. This collaborative initiative will improve our capability, jointly with our suppliers, to uphold our CSR commitments and obligations.

- Through the PCSI, Sanofi participates in two major work programs:
- the supplier shared audit program; and

the supplier performance improvement program: to establish formal industry guidelines and support suppliers to raise their capability to address ethical, labor, health and safety, and environmental issues.

In addition, Indian and Chinese suppliers are regularly trained through the PSCI group on the following topics: pharmaceutical residues in the environment, antimicrobial resistance, environment and safety, process safety and industrial hygiene. In 2022, 28 of Sanofi's Indian suppliers of active ingredients and 67 of Sanofi's Chinese suppliers of active ingredients participated. In addition, in December 2022, in collaboration with PSCI, Sanofi organized a training on water stewardship, which was attended by 73 Indian suppliers and CMOs of active ingredients.

8.1.8.Supplier Diversity

In 2022 we hired a Head of Global Supplier Diversity to ensure we achieve our diversity targets. We launched our Global Supplier Diversity strategy in procurement to strengthen communities' economic engagement and create a positive impact to increase the inclusion of historically disadvantaged or under-represented groups in our sourcing processes. A Supplier Diversity Governance Council was also launched, with monthly operations meetings and quarterly leadership council meetings to discuss the metrics and gaps, celebrate successes, and showcase small and diverse suppliers and external advocacy agencies. From a systems perspective, we launched a "Cockpit" dashboard that provides clear insights into our spend with specific supplier diversity tags.

We strengthened our partnership with MSDUK (a certifying body for European supplier diversity) and WeConnect International (certification available in more than 50 countries), to increase our collaboration and engagement with women-owned businesses (at least 51% owned, managed, and controlled by one or more women), and support women's economic empowerment. On International Women's Day, March 8, 2022, we made a public commitment to:

- double our woman-owned business spend by 2025; and
- spend over €1.5 billion (approximately 10% of our global expenditure) with small and minority-owned businesses by 2025.

In 2022, our supplier diversity spend was approximately €1 billion, and our women-owned business spend approximately €87 million.