VIGILANCE PLAN

GRI :

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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 Group'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.

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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 Group'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.

Two meetings were held in 2020, at 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 Ethics 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 report the incident by identifying themselves. This identification facilitates the investigation process. If a Sanofi employee chooses not to reveal his or her identity, an anonymous report can be sent. The system is also open to third parties who interact with Sanofi. Each alert, regardless of its source, received via the alert system or any other channel, is investigated internally in accordance with a methodological protocol defined by the alert management policy. If, at the end of the internal investigation, the allegations are confirmed, corrective and/or disciplinary action is taken. To ensure that these actions are determined in a coherent and harmonized manner, the company has put in place a policy formalizing the overall framework for corrective and/or disciplinary actions.

In 2020, the E&BI Directorate received 718 alerts, of which, following investigations, a total of 352 alerts were found to be well founded. These resulted in 85 dismissals and resignations for misconduct.

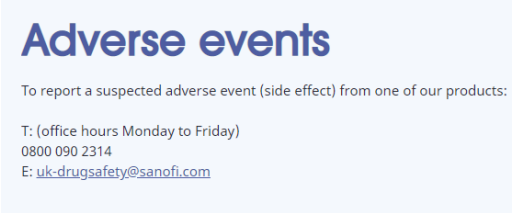
Focus on alerts related to human resources (harassment, violence in the workplace...) and discrimination:

- 830 alerts in all countries where Sanofi operates, since January 1, 2015, which represents 32% of total alerts.
- - Resulting in 298 confirmed HR cases that resulted in either employee dismissals (28%), reprimands (35%), training and coaching (20%), or process improvements.

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]



[Royaume-Uni]

[Inde]

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;
(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 freedoms	**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 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; and
- report to the regulatory authorities on a timely basis, in accordance with international and local regulatory requirements and our own Global Quality standards.

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.

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 benefit/risk approach protects patients and consumers by ensuring that our scientific communications are transparent, robust and credible. 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.

3.1.2. Politicy 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 worldwide quality documentation architecture in place, to ensure that all our pharmacovigilance activities comply with official regulations.

GPV is closely involved in many 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 we continue to apply best practice in the changing landscape, GPV has made significant strategic changes to its governance structure. We have identified the following strategic areas as having the highest priority:

- deploying an individual skillset development model so that our pharmacovigilance staff are up to speed with the latest regulatory and scientific practices, and qualified to meet future needs;
- delivering an ambitious technological development plan to automate and apply artificial intelligence to pharmacovigilance data. This was seen as a pre-requisite for managing not only the growing volume of data but also the diversity of data sources, including social media and patient support programs. 2020 saw the live rollout of the AI-based automated pharmacovigilance data management project, with highly satisfactory results in terms of data processing quality and accuracy, as well as productivity gains. During 2021, the technology will be ramped up as subsequent phases of the project are rolled out;
- extending our structured approach to benefit/risk profile evaluations, relying, if necessary, on population-based epidemiological statistics.
- optimizing the mechanisms used to detect and evaluate potential signals associated with the use of our products; and
- completing the refocusing of our in-house expertise on novel products with fast-changing benefit/risk profiles, by phasing in a new outsourced scientific platform dedicated to the monitoring of mature products or therapeutic classes. This model means we can focus our in-house resources on high-priority tolerance issues for the products we regard as the most critical in terms of patient needs and regulatory requirements.

3.1.3. Performance indicators

Signals assessed	2020	2019	2018(a)
Total signals	344	395	255
Of which PRAC/HA signals (b)(c)	125	204	110

(a) Period: January-November 2018.

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

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

Pharmacovigilance audits and inspections conducted in 2020:

- Number of audits: 33.
- Number of inspections: 5.

New performance indicator: quarterly submissions of individual pharmacovigilance cases to the European healthcare authorities by the regulatory deadline:

- Q1 2020 : 98,2 %.
- Q2 2020 : 98,2 %.
- Q3 2020 : 99,5 %.
- Q4 2020 : 99,2 %.

3.2. 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 4.2.2, “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).

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.

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 34 inspections conducted on our clinical research activities in 2020 resulted in regulatory action. The number of regulatory inspections was around 50% lower in 2020 than in 2019. The COVID-19 pandemic, and the resulting lockdowns and travel restrictions, meant that procedures had to be adapted so that data and documents could be shared electronically, in accordance with the relevant requirements relating to confidentiality and data security.

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.
- 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 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.

Around 70% of our workforce (mainly in production and R&D) continued to work on site, to ensure continuity of supply of our medicines and deliver on our public health mission.

HSE units at site level were called upon extensively as part of our COVID response, refocusing on the fundamentals and prioritizing business continuity. Our HSE network adapted to COVID-related restrictions by using online training, conducting virtual audits, developing ten onboarding modules, and creating a webinar on preventing accidents as people returned to work post-lockdown and during summer shutdown works. Nevertheless, our HSE teams remained fully mobilized to ensure continuity in production and in critical R&D activities.

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.

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

Sanofi also has in-house analytical laboratories, such as the Aramon facility in France. Staffed by a team of experts, the lab classifies the level of exposure of people to active substances; analyses environmental discharges from our sites; evaluates dangers associated with processes and classifies dust hazards and dust filtering equipment. The Aramon laboratory also develops specific analytical methods.

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 cmicals, biosafety hazards and radiation, and physical stress factors;
- 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):

The chemical manufacturing sites in Aramon, Sisteron and Vertolaye (France), the facilities at our industrial platform in Frankfurt am Main (Germany), and our chemical production facility in Budapest (Hungary) are all 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 three French sites mentioned above 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 five 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.

	2020	2019
Number of internal HSE audits, including Biosafety	**38**	24
Number of auditors with IRCA accreditation	22	23
Number of employees who have performed audits	80	81

By complying with Sanofi standards, sites may, if they wish, obtain official recognition of their commitment through international certifications: ISO 14001 (Environmental Management) and OHSAS 18001 (Occupational Health & Safety).

To further our commitment to energy management, we also encourage our sites to obtain ISO 50001 (Energy Management).

Similarly, we have been tightening our road safety policy since 2017 by encouraging our sites to obtain ISO 39001 (Road Traffic Safety). Two sites have already been awarded ISO 39001 certification.

In 2020, 50 of our sites had one or more certifications: ISO 14001 (38 sites), OHSAS or ISO 45000 (21 sites), and ISO 50001 (28 sites). This represents 60% of our employees in Industrial Affairs, R&D, and corporate HQ premises.

In addition to internal verifications and audits, our sites are also subject to regular inspections by local authorities and to regulatory verifications by third parties on specific issues. For example, 139 visits were carried out by technical experts on behalf of Sanofi's insurers during 2020, plus a further 45 remote diagnostic reviews during the period when travel was restricted because of the COVID-19 pandemic.

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 33 datasheets were distributed in 2020 to the whole global HSE network.

A campaign launched in 2018, focusing on preventing trip and slip hazards and other falls, significantly reduced accidents of this kind by 17% in 2019 (versus 2018), and by 47% in 2020 (versus 2019).

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

4.6.2. Road safety

During 2020, the travel restrictions imposed around the world due to the COVID-19 pandemic led to a reorganization of working practices and widespread use of remote communication. As a result, the distance covered by our medical reps on business trips fell by 32% relative to the previous year.

The practical training cycles originally scheduled were disrupted and replaced by online training and awareness sessions.

As each lockdown ended and field visits resumed, specific safety refresher courses were organized before employees took to the road again. Our road safety committees continued to be mobilized everywhere in the world, pursuing the actions that we have been taking over several years. Consequently, road accident injuries fell by 68% (16, versus 50 in 2019), even though the distance travelled fell by only one-third.

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).

Other risk factors associated with issues, such as noise, vibration and ergonomics are also examined.

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 recognized within Sanofi during 2020 was the musculoskeletal disorder category.

The number of occupational diseases is decreasing following the rollout of an ergonomics program to prevent such disorders.

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.

Highlights of 2020 include:

- Training delivery was adapted to meet the challenges of the COVID-19 pandemic, with face-to-face sessions replaced by remote learning, including modules on auditor training; leadership and safety culture; managerial safety visits; trainer training; and basic and intermediate ATEX (explosive atmosphere).
- The rollout of the Safety Culture program ("Rules that Save Lives"), which was launched in 2019, continued through 2020; 84,408 people have received training, or more than 95% of our global workforce. Our local trainers continued to roll out the Managerial Safety Visits program at all sites.
- Training modules to support employees resuming onsite work were developed and translated into several languages for our commercial operations; 11,188 people received training.
- An onboarding program for HSE managers was developed and rolled out remotely worldwide from October 2020. Around thirty HSE employees have started or completed the program to date.
- For technical and regulatory training, we developed basic-level e-learning modules (one theory, ten practical) on risk prevention in explosive atmospheres, and delivered them in 15 languages. 1,225 people received training worldwide.
- The machine safety program was disrupted by COVID-19, with only 39 people receiving training worldwide.

4.6.5. Occupational injury/disease indicators

TOPIC	AMBITION	PROGRESS		CONTRIBUTION TO SDGs
		2020	2019	
Health and safety in the workplace	Reduce the total occupational injury frequency rate (any employee) below 2 by 2020	1.7	2.2	**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 2020	1.1	1.5	

	2020	2019
Lost time injury frequency rate (a) – Sanofi personnel	0,9	1,3
Lost time injury frequency rate (a) – any employee (b)	1,1	1,5
Total occupational injury frequency rate – Sanofi personnel	1,3	1,7

Total occupational injury frequency rate – any employee (b)	1,7	2,1
Number of death	0	2
Number of occupational diseases reported	34	28

(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) All employees include Sanofi employees, temporary workers and subcontractors.

Our safety performance was better than in previous years, mainly due to fewer falls and vehicle accidents. Another factor was an increase in teleworking among administrative and sales staff due to the COVID-19 pandemic.

A total of 34 occupational diseases were reported to local authorities in 2020: 26 in France, 6 in Germany and 2 in the United States, all countries with well-established recognition and reporting systems. Most of the occupational diseases related to musculoskeletal disorders. Nine cases from 2019 were reported late and have been added to the 2020 data.

5. FUNDAMENTAL HUMAN RIGHTS AT WORK

We employ nearly 100,000 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.

In dealing with human rights, we refer to the following ILO 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 must comply with regulatory obligations on human rights; these include international standards, such as the United Nations Guiding Principles on Business and Human Rights and national regulations, such as the French Duty of Vigilance law.

We need to identify the nature and extent of potential human rights violations in every country in which we, our suppliers and direct subcontractors operate, and 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.
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 used to define human rights are linked to the characteristics of the workforce.

To evaluate the criticality of risks, we determined several inherent risk factors: level of qualification, working conditions, potential presence of vulnerable workers, and the characteristics of countries where we operate (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, 7 (representing more than a quarter of the Sanofi workforce) have already been subject to audit.

In 2020, 16 countries (Algeria, Bangladesh, Brazil, China, Colombia, Egypt, India, Indonesia, Mexico, Pakistan, Russia, Saudi Arabia, South Africa, Thailand, Turkey, Vietnam) responded to the internal control questionnaire. The main findings are summarized below:

Issue	Findings
Child labor 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	No major compliance breaches reported
Travail forcé 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	No major compliance breaches reported Difficulties reported by some countries relating to issues around decent wages and audit of recruitment agency practices.
Working hours Main control points: - Compliance with ILO working hours standards: weekly, daily, overtime, paid leave, maternity leave.	Reports of difficulties applying standards due to local legislation in certain countries.
Freedom of association Main control points: - No discrimination based on trade union membership, and no abusive practices against worker representatives. - Respect for the right to collective bargaining	Reports of difficulties applying standards due to local legislation in certain countries.

Corrective action plans are being drawn up within the entities concerned. Group-wide initiatives will be rolled out in 2021 to help Sanofi subsidiaries address the difficulties identified in applying standards. We will draft a global policy on fundamental human rights at work, to collate and reinforce the requirements contained in our existing policies.

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, Human Resources, Information Technology & Solutions, Finance, Commercial Services, Industrial Affairs, and our Global Business Units.

6.2. Politicies 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.

Our Global Privacy Office uses the PRIMA (PRivacy IMpact Assessment) tool, which is made available to any Sanofi employee who needs to process personal data. PRIMA enables users to check their project for compliance with data protection regulations and Sanofi policy, determine any corrective action required, and update the Sanofi data processing register. This guarantees an audit trail for all projects involving the processing of personal data. We have also developed awareness-raising videos and training modules (updated in 2019) so that all our employees know the importance of issues around the protection and transfer of data within Sanofi.

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-By-Design 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.

This year, Sanofi again completed the Water Security questionnaire of the Carbon Disclosure Project (CDP), obtaining the highest rating of A. This recognizes our achievement in consistently reducing the water footprint of our industrial operations over several years.

Utility services (steam, process water and cooling systems) are by far 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.

Water is also 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 such cases, a range of water treatment processes are in place at each site to guarantee a very high degree of purity prior to use.

We seek to use this resource responsibly, by implementing water management plans at our sites, and pay particularly close attention to sites identified as priority in terms of water-related risks, especially in water stress zones.

In 2020, we launched a large-scale campaign to update water risk mapping across all our industrial sites, using a customized tool developed with the help of an external consultant. There are many water-related risks, but they can be classed in three main categories: physical, regulatory and reputational. An in-depth analysis, based on our own local data and a comprehensive independent review, has helped us fine-tune our list of priority sites potentially subject to water-related risks and those where additional investigation is needed at local level to confirm the situation. This list will be distributed internally during 2021. The four sites regarded as priority sites, as of the end of 2020, are Brindisi (Italy), Vertolaye (France), Karachi (Pakistan) and Jakarta (Indonesia).

7.1.2. Water consumption

Water used during manufacturing and heat exchange (heating or cooling for processes, with no contact with manufacturing) is essentially withdrawn directly by Sanofi 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.

Nearly 42% of our sites cut their water withdrawal in 2020, resulting in a reduction in water withdrawal of 5% for the year and 22% versus 2015, well above our 10% objective

Water consumption (millions of m3 per year)	2020	2019	2015 (baseline year)
Withdrawal of surface water (lakes, rivers)	8	8,9	11,2
Withdrawal of groundwater	17,7	23,3	23,4
Withdrawal of water from public supply	7,5	8,3	8,2
Other sources	0,3	0,2	_
TOTAL	33,5	42,8	42,7

Withdrawals at our four priority sites were just under 6.0 million m3 in 2020, 16% lower than in the previous year.

7.2. Biopiracy

Sanofi is committed to complying with conventions on the protection of biodiversity and combatting biopiracy. Compliance with local regulations derived from the Nagoya Protocol requires coordinated efforts across all Sanofi entities. In 2015, we set up a project team to track worldwide implementation of the Nagoya Protocol and analyze its implications for our operations. At that stage, the focus was on identifying the biological materials we use to discover, develop, manufacture and package our products, and on documenting the country of origin and date of acquisition, in accordance with our own guidelines. During 2016 and 2017, the project team drafted documents 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 were provided with specific training and awareness programs in 2017. 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

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. Politicies 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.
- 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) “Roadmap 2020” 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.

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 airborne 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 2020, this program covered 50% 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. We have drawn up an initial priority list of over 160 active ingredients. To date, our evaluation program has already covered 37% of these substances.

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

The data reported correspond to effluents reaching the environment (i.e., after internal and/or external treatment, depending on the site). Chemical oxygen demand (COD) is the primary environmental indicator of effluents. If no information on external treatment is available, a conservative purification rate of 50% is applied as a default.

Wastewater discharge (tonnes)	**2020**	**2019**
COD	1982	2243

Total COD discharges from our sites fell by around 12% in 2020. Decreases of varying degrees were recorded at 46 of our sites. This trend is consistent with the year-on-year trend in water withdrawal, which also fell slightly.

We work continually to improve the quality, relevance and accuracy of the metrics we use. For COD in particular, we are planning to report the annual quantity discharged by each site as measured within the site boundary, whether the site discharges directly to the environment (after onsite treatment) or indirectly via municipal drainage systems.

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

Solvents (Tonnes)	**2020**	**2019**
Solvents used	178 381	184 472
Percentage of regenerated solvents	62%	62%

Volatile organic compounds (VOCs) (tonnes)	2020	2019
VOCs (estimated)	2893	2947
Sox – direct emissions	176	203

NOx(Tonnes)	2020	2019
NOx – direct emissions	491	494

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

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 2020 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 2020, Sanofi spent €55 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 €713 million as of December 31, 2020, compared with €737 million in 2019. 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 2020 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	2020	2019	2018
Procurement spend (€ billion)	14,8	14,5	15,6
in OECD countries	13,3	12,2	13,3
in non-OECD countries	1,5	2,3	2,3
Number of suppliers	54 507	68 000	86 000
Number of countries where we have suppliers	138	152	157

Sanofi is a member of the Pharmaceutical Supply Chain Initiative (PSCI) which aims to improve practices at industry-specific suppliers by establishing common standards, providing support and training programs for suppliers, and arranging shared audits.

In September 2020, PSCI held virtual training courses for Indian and Chinese suppliers on: pharmaceutical residues in the environment and antimicrobial resistance; business ethics and human rights; safety and the environment; safe processes; and occupational health. In total, 95 of our suppliers of active ingredients took part (49 from India, and 46 from China).

Under the auspices of PSCI, we worked with our peers to develop the first-ever environmental and social risk mapping exercise for a dozen natural or mineral commodities that are used and shared by our industry, such as palm oil and fish oil.

We have also signed up to the Together for Sustainability (TfS) initiative, a worldwide program to evaluate and improve sustainable procurement practices adopted by suppliers. Under the TfS initiative, supplier evaluations and audits are carried out, and the results shared between TfS members via a collaborative online platform.

Our Responsible Procurement approach requires our suppliers to adhere to Sanofi's commitments on human rights, health and safety and the environment via our Suppliers Code of Conduct, with which all our suppliers must acquaint themselves. The Code of Conduct was updated in 2020 to include data protection and a requirement for our suppliers to secure commitments from their own suppliers. In addition, we conduct anti-corruption due diligence before doing business with at-risk suppliers.

A supplier onboarding application is currently being rolled out, which by the end of 2020 covered around 60 countries. The procurement risk mapping exercise described below has been integrated into this new application, allowing for upfront evaluation of new suppliers on health and safety, environmental and human rights criteria. All new suppliers have to complete a self-assessment questionnaire so that we can be sure they meet our requirements.

All 250 procurement categories were evaluated during 2018 and rated on a scale from 1 to 4 in terms of their inherent risk to health and safety, the environment, and human rights. Inherent risk is defined as the external business-related risk (regardless of the country where that business is carried on) that suppliers in a given procurement category will endanger health and safety, violate the human rights of their workers, or cause harm to the environment.

The risk rating reflects:

- for health and safety: the number of people potentially affected, and the severity and irreversibility of the accidental or chronic harm caused;
- for the environment: the extent and irreversibility of the negative consequences (in terms of pollution and consumption of natural resources) for the environment, communities and biodiversity (not necessarily limited to the site itself); and

- for human rights: the characteristics of the labor force (level of qualification, headcount, extent of reliance on temporary labor), and the human rights sensitivity of the products used (supply chain).

An overall composite rating was calculated for each procurement category and around forty were classified as inherently high-risk in terms of environmental protection, health and safety, and human rights. These categories were associated with waste management, demolition, depollution, major construction works, hazardous products, active ingredients, natural products, pharmaceutical subcontracting, clinical trials, transport and distribution, site operations, security services, travel and events, and recruitment agencies.

This risk mapping was updated in 2020, enabling us to determine response typologies for each category identified as being at risk with reference to the vigilance plan (health and safety, environment and human rights). The response depends on the risk rating, the country, the characteristics of the service provided (such as on/offsite, the service-provider's organizational structure, recurrence, etc.) and the volume of spend. Examples of potential risk management responses include audits (by our internal auditors, or via the PSCI or TfS industrywide initiatives), risk assessments, prevention plans or targeted awareness campaigns.

Suppliers identified as being in the highest risk categories have their CSR performance assessed by an external service-provider. The results of those assessments are fed back into the procurement risk management process, driving constant improvement among our supplier base. The process covers more than 200 suppliers a year, with the aim of covering 100% of our high-risk strategic suppliers by the end of 2022.

We assessed 212 suppliers in 2020. Of these, 180 were undergoing a reassessment, and 54% of those had improved their rating after following an action plan.

Despite COVID-19, we were able to continue our supplier evaluation program in compliance with lockdown restrictions by conducting remote virtual audits, retaining the services of accredited local firms, or retrieving shared audits from industry initiatives to which we belong (PSCI and TfS).

We also aim to have completed audits of all our suppliers of high-risk critical active pharmaceutical ingredients (APIs) and all our contract manufacturing organizations (CMOs) by the end of 2021.

	2020	2019	2018
Number of Sanofi CMO audits	42	72	64
Number of audits of active pharmaceutical ingredient (API) suppliers	44	87	90
Number of shared audits (PSCI) of miscellaneous suppliers: packaging and CRO categories (a)	35	-	-

(a) Data available from 2020

Results from these audits for the 2016-2020 period showed that one-quarter of the suppliers failed to meet the required standard, mainly suppliers based in India and China. All of these suppliers are required to follow a corrective action plan. During the 2016-2020 period, 83 API suppliers and 172 CMOs were reassessed, and nearly half of these had improved their performance.