



Annual Activity Report 2024

DG Health and Food Safety (SANTE)

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FOREWORD

2024 was a significant year for DG SANTE, marking the end of a very challenging yet extremely productive mandate for our portfolio and our 25th anniversary as a DG. Both of these milestones served to illustrate how far we've come in EU health and food safety policy.

The Communication on the European Health Union highlighted just how much progress we've made in EU health policy in recent years. The EU is better prepared than ever to deal with health crises and to protect the wellbeing of its citizens, guided by the One Health approach to address risks across human, animal, and environmental domains. This was evident in our coordinated response to the global Mpox emergency, our diligent management of the avian influenza situation and our swift reaction to other health challenges as they arose. The designation of the first six European reference laboratories for public health in March further bolstered the EU's arsenal for preparedness and response. And the launch of a €50 million joint action on antimicrobial resistance was key to supporting Member States' commitments under the 2023 Council Recommendation on AMR. At global level, the Commission's contribution to the revised International Health Regulations and the UNGA Political Declaration on antimicrobial resistance were essential to strengthen cooperation in the face of serious health threats.

But the Health Union is also about the adoption of the European Health Data Space (EHDS), which will unlock the benefits of digitalisation to revolutionise our healthcare systems. It is about the new rules on Substances of Human Origin (SOHO) which upgrades patient safety across the EU. The ambitious pharmaceutical reform, on which we actively supported negotiations in 2024, will improve access, availability, and affordability of medicines, and support the competitiveness of our industry. And the new Health Technology Assessment Regulation will significantly improve patient access to new and effective health technologies. In 2024, DG's SANTE's activities on these initiatives, along with many others, lay the ground for a more competitive, innovative and resilient health ecosystem in Europe in the years ahead.

Europe's Beating Cancer Plan, a central pillar of our Health Union, also advanced full force, with the Recommendations on smoke-free environments and on vaccine-preventable cancers. In addition, continued funding of dozens of projects under the EU4Health programme, a new joint action on cancer screening, and our work to develop a Cancer Inequalities Register will all bring real improvements when it comes to preventing, detecting and treating this insidious disease.

The fight against animal diseases is another key component of our One Health policy and in 2024 DG SANTE continued to provide considerable support to Member States in this domain. A positive result from this was a 26% rise in disease-free approvals, thanks to the EU's mandatory eradication requirements. Our work to improve animal welfare continued with the negotiations on the proposals on dogs and cats and on transport, which we made at the end of 2023. In the area of plant health, we welcomed agreement on new rules, which will boost our protection against pests and diseases that threaten agricultural sustainability and food security.

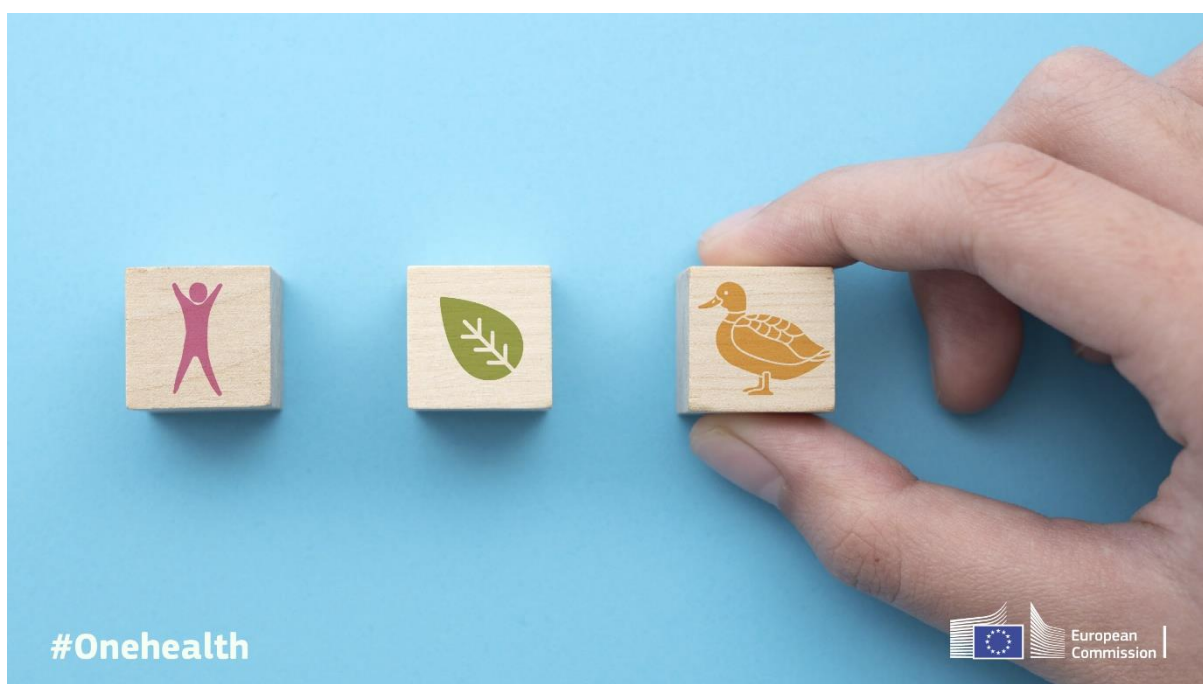
In the important area of food safety, we took bold steps to strengthen consumer protection, including bans on bisphenol A (BPA) in food contact materials and on smoke-flavourings in food. We also continued to ensure the implementation of the vast body of EU food safety legislation, performed audits and verified corrective actions and, thanks to our rapid alert systems, were ready to react when food safety risks arose.

These are just some of DG SANTE's deliverables in 2024, to protect our citizens, support our farmers and enhance EU competitiveness. I would like to conclude by thanking all the colleagues in DG SANTE for their dedication to our portfolio and professionalism in their work. Our commitment to the health, safety and wellbeing of EU citizens remains as strong as ever as we embark on a new Commission mandate.

Sandra GALLINA, Director General for Health and Food Safety

THE DG IN BRIEF

In 2024, the Directorate-General for Health and Food Safety (DG SANTE) continued to contribute to two of the general objectives of the first von der Leyen Commission (2019-2024): [The European Green Deal](#) and [Promoting Our European Way of Life](#). It strives to protect **human, animal and plant health and animal welfare** and to promote a high level of **safety and sustainability along the food supply chain**. Our [mission](#) supports the Commission's priorities for public health and food safety and sustainability, as well as growth and competitiveness in two of the EU's most important economic sectors – health and food. In 2024, these commitments to complete the European Health Union and ensure a high level of food safety were reaffirmed in the Political Guidelines 2024-2029 and in Commissioner Várhelyi's mission letter. Our activities are shaped by the [Treaty on the Functioning of the European Union \(TFEU\)](#) and principally linked to Articles [168](#) (public health), [43](#) (agricultural policy), [114](#) (internal market), and [13](#) (animal welfare). With the appointment of the new College, that took office on 1 December, DG SANTE is prepared to embrace new priorities that align with the evolving strategic vision and objectives.



DG SANTE continues to strengthen the **European Health Union**. It plays a leading role in health security, managing cross-border threats to health at EU level and coordinating and supporting action to prepare for and respond to such threats. Also, DG SANTE manages **EU health legislation**, which includes the rules on the authorisation of human and veterinary medicines and certification of medical devices, those applicable to organs, blood, tissue and cells, clinical trials, falsified medicines, digital health including the European Health Data Space, tobacco control, to cross-border movements of patients, and those that allow cooperation and integrated work among Member States on eHealth and rare diseases. Our activities in this area are also non-regulatory and supported by dedicated funds. DG SANTE leads the Commission's action directed at ensuring the **safety of the food supply chain and its transition towards a sustainable food system**.

DG SANTE is the lead DG for European Health and Digital Executive Agency (HaDEA) which implements most of the **EU4Health Programme** and **the Food Safety strand of the Single Market Programme** as well as parts of Horizon Europe (Pillar II), the Digital Europe Programme and Connecting Europe Facility. DG SANTE is also a partner DG to the following EU decentralised agencies: the [European Medicines Agency \(EMA\)](#), the [European Food Safety Authority \(EFSA\)](#), the [European Centre for Disease Prevention and Control \(ECDC\)](#), the [Community Plant Variety Office \(CPVO\)](#) and the [European Chemicals Agency \(ECHA\)](#) for its activities related to biocidal products. DG SANTE also has a seat on the Management Board of the [European Union Drugs Agency](#).

The [EU4Health Programme](#), with a budget of EUR 752.4 million in the 2024 work programme (including EFTA credits), is the main instrument to fund the Union health initiatives. 37.1 % were attributed to DG SANTE and 62.9 % to HERA. EU funding for food and feed safety is governed by the [Single Market Programme](#). Expenditure covers animal and plant health programmes, emergency measures for animal and plant disease outbreaks, measures for reduction of food waste and antimicrobial resistance, training and official control activities. The total amended 2024 budget of the Food Safety strand of the Single Market Programme amounted to EUR 266 million for the parts implemented by DG SANTE and HaDEA.

At the end of 2024, DG SANTE had 743 statutory staff and 63 seconded national experts. 2024 saw the appointment of a Deputy Director General and two Directors. DG SANTE has filled all its senior management positions.

EXECUTIVE SUMMARY

This annual activity report is a management report of the Director-General of DG SANTE to the College of Commissioners. Annual activity reports are the main instrument of management accountability within the Commission and constitute the basis on which the College takes political responsibility for the decisions it takes as well as for the coordinating, executive and management functions it exercises, as laid down in the Treaties⁽¹⁾.

A. Key results and progress towards achieving the Commission's general objectives and department's specific objectives (executive summary of section 1).

1. A European Green Deal

Food and feed safety

In 2024, DG SANTE continued to enhance food safety in Europe, fortifying consumer trust in food products. Notable regulatory advancements to protect public health included the adoption of hygiene standards for meat aging and setting maximum contamination levels for antimicrobials in animal feed or of a Regulation as regards *Listeria monocytogenes*, setting up limits of the presence of this pathogen in ready-to-eat foods. An evaluation of EFSA's performance mandated by Article 61 Regulation (EC) No 178/2002, was also initiated, aiming for completion by 2026.

DG SANTE prioritised the streamlining of existing regulations, aligning with President von der Leyen's goal to reduce reporting obligations by 25%. Noteworthy simplification initiatives included amendments in the Plant Health Law, modifications to health certifications for intra-EU animal by-product movements and to remove further administrative burdens, particularly concerning ionizing food irradiation checks. These initiatives are part of a broader strategy to simplify and rationalize reporting requirements, aiming for a significant reduction also beyond 2024.

On animal health, DG SANTE maintained its integrated approach to disease prevention and eradication, achieving a 27% rise in approvals of territories, zones or compartments free of specific diseases. New rules under the EU Animal Health Law were adapted to reflect current disease scenarios. The health status for certain diseases has improved in a number of regions. Additionally, DG SANTE continued to adapt EU rules and provide financial support for controlling transmissible animal diseases, emphasizing a One Health surveillance system for cross-border pathogens.

Plant health efforts focused on managing pests like Citrus Black Spot and *Xylella fastidiosa*. The revised Plant Health Law aimed at enhancing EU pest control and simplifying procedural burdens. The DG also addressed unsafe substances in food, e.g. refusing renewal of authorisations for eight smoke flavorings due to genotoxicity concerns.

In 2024, DG SANTE conducted 143 controls on compliance to EU rules on food safety, identifying and addressing short g comings. Despite a lower-than-targeted closure rate for

¹ Article 17(1) of the Treaty on European Union.

audit recommendations, ongoing monitoring ensures continuous improvement. Rapid alert systems were further developed, including a significant advancement in the Animal Disease Information System, enhancing data quality and easing reporting burdens for EU Member States.



Sustainable food systems – the ‘Farm to Fork’ Strategy

In 2024, DG SANTE engaged in numerous initiatives to enhance the sustainability and efficiency of the EU's agricultural and food systems. Following the launch of the Strategic Dialogue on the Future of EU Agriculture, DG SANTE contributed to the preparation of the Vision for Agriculture and Food and continued to coordinate the work (initiated by JRC in 2022) on the development of a framework for monitoring the sustainability resulting in the publication of a dashboard of indicators which aims to give a comprehensive and cross-sectoral overview of the food supply chain.

Efforts to reduce pesticide dependency continued despite the European Parliament's rejection of the Commission proposal for an ambitious Sustainable Use of Pesticides Regulation. The DG focused on implementing existing rules, supporting Member States with training, inspections, financial resources for increasing capacity to conduct risk assessments and continued its work on facilitating market access for biological pest control substances and low-risk chemicals.

To combat antimicrobial resistance (AMR), DG SANTE pursued a 50% reduction in the overall EU sales antimicrobial sales for animals and aquaculture by 2030, with new regulations and reporting requirements in place. The Commission also adopted a Delegated Act to manage cross-contamination in non-targeted feed.

DG SANTE addressed food waste reduction, in line with the UN Sustainable Development Goals. Negotiations in the Parliament and the Council on binding EU targets progressed, and campaigns like "Zero Waste, More Taste" were launched to engage consumers. Support was provided to stakeholders and Member States through funding and initiatives to improve food

waste measurement and prevention programs.

Enhancing animal welfare in the EU remained another priority, with legislative proposals on the welfare of dogs and cats, and animals in transport. An Animal Welfare Expert Group and an Animal Welfare Working Group were established by DG SANTE, to allow for an exchange between the Commission and the Member States of practical matters related to animal welfare, as well as the preparation of tertiary legislation.

Initiatives to fight agri-food fraud, empower consumers with better food information, and support innovation in the food chain were also pursued. DG SANTE authorised novel foods, implemented the GMO regulatory framework, while also supporting negotiations in the Parliament and the Council on a new Regulation on plants obtained by certain new genomic techniques (NGTs), adopted a ban on the use of bisphenol A (BPA) in Food Contact Materials (FCM) following an EFSA opinion, while continuing the preparatory work for a revision of the FCM Regulation. These efforts contribute to a more sustainable, transparent, and innovative EU food system.

International promotion of EU food safety standards

In 2024, DG SANTE focused on enhancing multilateral and bilateral relations to promote food safety, sustainability, and quality standards globally. Key efforts included active participation in international organisations like the WTO, WOA, Codex Alimentarius, and the Convention on Biological Diversity, where the DG advocated for the One Health approach and aligned EU legislation with international standards. Bilaterally, DG SANTE successfully negotiated sustainable food system chapters in trade agreements with India (chapter concluded), Thailand, and the Philippines. Additionally, collaboration with South Korea, Switzerland, and the UK led to improved trade facilitation and regulatory alignment.

2. Promoting our European Way of Life

In 2024, DG SANTE undertook initiatives to simplify regulatory frameworks and enhance EU health policies. In the area of non-communicable diseases, the 'Healthier Together' initiative provides the strategic framework to support Member States in tackling non-communicable diseases. The Network of Expertise on Long COVID addressed related challenges. Support for Ukraine included medical evacuations and mental health aid, with over EUR 30 million mobilised. DG SANTE also coordinated EU health responses to conflicts, launched mental health initiatives, and expanded EU4Health funding, fostering international collaboration and aligning health standards across Europe.

Diminishing the impact of cancer in Europe

In 2024, DG SANTE advanced its Europe's Beating Cancer Plan with a focus on vaccine-preventable cancers, tobacco control, and cancer screening. A Council Recommendation encouraged EU Member States to boost HPV and HBV vaccination, supported by a €20 million EU4Health initiative. Tobacco control efforts aimed for a smoke-free generation by 2040, extending smoke-free policies to outdoor areas and emerging products. The EU tobacco traceability system was expanded to curb illicit trade. Cancer screening initiatives targeted breast, colorectal, and cervical cancers, with new European guidelines and campaigns like #GetScreenedEU reaching millions. Progress was showcased at a World Cancer Day event.



Patients' access to safe, innovative and affordable medicines and medical devices

In 2024, DG SANTE continued implementing the Pharmaceutical Strategy for Europe, a patient-centered strategy that aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness. A key action was to support the co-legislators in the negotiations to reform the pharmaceutical legal framework, including medicines for children and rare diseases, to enhance flexibility and adaptability. The new fee Regulation was also adopted by the co-legislators in February 2024. DG SANTE started preparing for a Biotech Act in 2026. The Union List of Critical Medicines was updated, and the Voluntary Solidarity Mechanism proved effective in supporting Member States facing severe shortages. 100 new human medicines were authorised and post-marketing processes were improved.

The DG continued monitoring the Clinical Trials Regulation, with the Clinical Trials Information System (CTIS) being now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. International cooperation saw the European Medicines Regulatory Network designated as a WHO Listed Authority.

The Health Technology Assessment (HTA) Regulation established a framework for EU-level cooperation, with four implementing acts adopted in 2024. On medical devices, the Commission launched a targeted evaluation of the impact of the legislation and amended regulations to improve availability and transition timelines. These efforts reflect a comprehensive approach to ensuring safe, effective, and accessible medicines and medical devices, enhancing regulatory frameworks, and fostering international collaboration.

Effective response coordination of serious cross-border health threats

DG SANTE is in charge of the Health Security Committee, which is by law the main EU body in charge of the coordination of prevention, preparedness and response planning for serious cross-border threats to health. Following the 2022 new Regulation on serious cross-border health threats, it was substantially upgraded and is now recognised by Member States as the central and formally entity where to discuss and prepare action to counter EU health crises. In 2024, DG SANTE further enhanced health security preparedness across the EU through the

implementation of the above-mentioned Regulation and they key work on the assessment of Member States' readiness. Seven country evaluations led by the ECDC were completed, culminating in a comprehensive report on prevention and preparedness shared with the Health Security Committee. DG SANTE also worked to evaluate the Regulation's effectiveness.

The EU4Health Programme supported Member States in improving disease surveillance, while European Reference Laboratories were designated to strengthen rapid detection and response capabilities. DG SANTE played a key role in coordinating the EU's response to the Mpox outbreak. The Joint Procurement Agreement for medical countermeasures was expanded with Moldova joining as the 38th signatory.

DG SANTE supported regulatory actions, policy-related activities and access to COVID-19 vaccines, and support Member States in ensuring successful deployment and sufficient uptake of such vaccines. The Commission extended the authorisation of Imvanex, the only vaccine against Mpox currently authorised in the EU, for use in adolescents and authorised the first-ever vaccine against Chikungunya virus. Antimicrobial resistance (AMR) was a priority, with initiatives like EU JAMRAI 2 and global collaborations aiming to reduce AMR-related deaths. DG SANTE's work aligned with the EU Global Health Strategy, emphasising universal health coverage and health system strengthening. It also engaged in civil-military cooperation on health security and collaborated internationally on health security and pandemic preparedness.

More effective, accessible and resilient health systems

In March 2024, the European Parliament and the Council reached a political agreement on the Regulation for the European Health Data Space (EHDS). Preparatory activities for EHDS implementation advanced, focusing on primary and secondary uses of health data. Three new Member States joined MyHealth@EU, and work continued on laboratory results services and the HealthData@EU pilot project.

DG SANTE also supported global digital health efforts, collaborating with international organisations and the US. Concurrently, DG SANTE assessed health investments in Recovery and Resilience Plans, emphasising healthcare access and workforce challenges.

The new Regulation on Substances of Human Origin (SoHO) was adopted, and initiatives addressed health workforce shortages. Efforts to improve cross-border healthcare awareness and the integration of European Reference Networks (ERNs) continued, with workshops and a new IT platform launched.

Throughout the year, SANTE's impactful communication campaigns (cancer screening, AMR, mental health, vaccination) social media and press activities have underpinned the delivery and implementation of key policy files. In particular our new Linked In presence helped to strengthen engagement and communication with stakeholders and other specialised audiences.

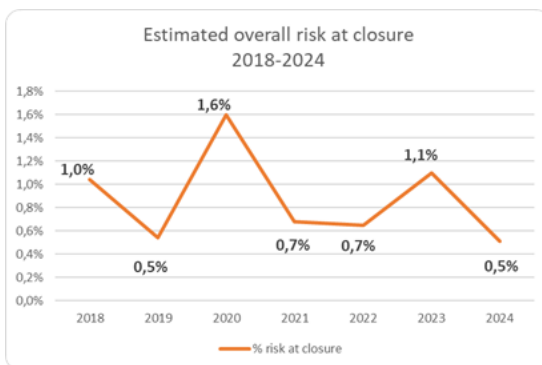
B. Key performance indicators

Result indicator 2.1.A: Age-standardised five-year net survival of cervical, breast and colorectal cancer

Explanation: Cervical, breast and colorectal cancer survival is one of the key measures of the effectiveness of health care systems in cancer care, reflecting both efficiency in early detection and the effectiveness of treatment.

Source of data: EUROCARE (Joint Research Centre) and CONCORD Programme, London School of Hygiene and Tropical Medicine

Baseline (2014)	Interim Milestone (2022)	Target (2024)	Latest known results (Situation on 31/12/24)
Cervical cancer: 63% (EU average) Breast cancer: 83% (EU average) Colorectal cancer: 59% (EU average)	Increase Increase Increase	Increase, with at least 2/3 of Member States above baseline	Baseline (2014) results are by far the most up-to-date figures available, coming as they do from CONCORD. A sustainable mechanism to obtain more timely results on survival rates is under investigation and has been identified and implemented through the CancerWatch Joint Action, which is intended to support the computation and delivery of updated survival and will be integrated in the European Cancer Information System (ECIS) by the end of 2026 when it is available.



KPI 2: Estimated overall risk at closure

The main key performance indicator of the control objective "legality and regularity" is DG SANTE's estimated overall risk at closure based on equivalent estimates to the detected error rates. In the last seven years, the overall risk at closure has not exceeded the materiality threshold of 2%.

C. Key conclusions on internal control and financial management

DG SANTE has systematically examined the available control results and indicators, [including those from supervised entities to which it has entrusted budget implementation tasks, as well as the observations and recommendations issued by the internal auditor and the European Court of Auditors. These elements have been assessed to determine their impact on management's assurance about the achievement of the control objectives. Please refer to Section 2 for further details.

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated. Improvements are necessary concerning minor internal control deficiencies related to ethics, staff allocation and professional development. In 2025, DG SANTE will reinforce its awareness raising efforts related to “ethics”, as identified in the action plan of the anti-fraud strategy, and further invest in ‘Be Well at Work’ initiatives. **The Director-General, in his capacity as Authorising Officer by Delegation, has signed the Declaration of Assurance.**

D. Provision of information to the Commissioner

In the context of the regular meetings during the year between DG SANTE and the Commissioner on management matters, the main elements of this report and assurance declaration, have been brought to the attention of Commissioner Várhelyi, responsible for Health and Animal Welfare.

1. KEY RESULTS and progress towards achieving the Commission's general objectives and DG's specific objectives

General Objective 1: A EUROPEAN GREEN DEAL

Specific Objective 1.1: Food and feed safety

In 2024, DG SANTE kept on developing, based on scientific advice delivered by the European Food Safety Authority (EFSA), the legal framework and policies to increase the level of food safety in Europe and prevent food crises, further consolidating European consumers' confidence. Examples are [Commission Delegated Regulation \(EU\) 2024/1141](#) and [Commission Delegated Regulation \(EU\) 2024/1229](#) or [Commission Regulation \(EU\) 2024/2895](#). DG SANTE has also launched preparatory work for the Commission's evaluation of EFSA's performance, due by March 2026.

Simplification of the existing regulatory framework was pursued. The DG achieved progress, in particular for national authorities in the Member States, related to digitalisation and automation, such as the relevant amendments in the Plant Health Law, or those of health certification at entry into the EU and formalities of intra-EU movement of animal by-products. The DG reduced administrative burden for Member States by removing the obligation of reporting annually the results of checks carried out in the ionising food irradiation facilities and at the product marketing stage².

DG SANTE continued implementing its plan to simplify and rationalise the reporting requirements and reduce burden on businesses and/or national administrations. The plan includes a list of concrete measures for 2024 and beyond to progress towards the 25% target. In addition to the measures on digitalisation mentioned above, DG SANTE started evaluating legislation on animal health with a view to identifying opportunities for further rationalisation. For more information on simplification initiatives (see Annex 2, Result Indicators 1.1.D and 1.1.E).

Ensuring animal health and managing and isolating outbreaks of major animal disease. In 2024, DG SANTE continued to actively pursue [an integrated approach to the prevention, control and eradication of animal diseases](#) that may be transmissible either to animals or to humans. On the prevention side, in 2024, following the implementation of mandatory disease eradication programs under the Animal Health Law, Member States achieved an improvement, with a 27% rise in the number of disease-free approvals.

DG SANTE continued the implementation of the EU Animal Health Law by adopting several rules, for example Delegated Regulation (EU) 2024/2623 supplementing Regulation (EU) 2016/429 as regards rules for approval and recognition of disease-free status of

² Publication in November 2024 of Directive (EU) 2024/2839 of the European Parliament and of the Council amending Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU as regards certain reporting requirements in the fields of food and food ingredients, outdoor noise, patients' rights, and radio equipment.

compartments keeping terrestrial animals. Some rules were also amended to adjust to the changed disease situation in the EU as for example amendment to Delegated Regulation (EU) 2020/688 providing possibilities for movements of ungulates due to the epizootic hemorrhagic disease. To ensure a smooth operation of the Animal Health Law, Implementing Regulation (EU) 2021/620 was amended 4 times to update disease-free statuses and eradication programmes. Implementing Regulation (EU) 2021/404 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted was adjusted 30 times. 5 substantial revisions of Implementing Regulations (EU) 2020/2235 and 2021/403 concerning model certificates relevant for the entry into the Union were implemented in 2024.



The health status for certain diseases has improved in a number of regions (e.g. the provinces of Agrigento and Matera in Italy achieved the infection with *Brucella abortus*, *B. melitensis* and *B. suis* free status and the province of Sassari in Italy achieved the infection with *Mycobacterium tuberculosis complex* free status). The Commission also launched in 2024 an external study that will feed into the evaluation of EU Animal Health Law. Paying specific attention to transmissible animal diseases, DG SANTE continued adapting EU rules to reflect the evolving disease situation and provide financial support for measures implemented in the EU and neighbouring non-EU countries.

The DG followed up the financial support to Member States for setting up a One Health-based coordinated surveillance system for certain cross-border pathogens. On the basis of a preliminary risk assessment by EFSA and ECDC, already 23 Member States applied for the grants to set up a coordinated surveillance system (2024 - 2026). Harmonised data collection and risk assessment by EFSA, in collaboration with ECDC, with a One Health approach will enable DG SANTE to identify future zoonotic threats for EU.

Outbreaks of major animal diseases did not relent in 2024 with however a decline in cases

of avian flu according to a report published in October by EFSA, ECDC and the EU Reference laboratory recording fewer infected wild birds last season, and much fewer infected poultry farms, thanks to enhanced preparedness and prevention. The EU also faced outbreaks of *peste de petits ruminants* in Greece, Romania and Bulgaria and sheep pox and goat pox in Greece and Bulgaria. African swine fever remains a challenge. Despite its eradication in Sweden and in Sardinia (Italy), disease control remains complicated in the absence of effective and safe vaccine.

Preventing plant pests. Prevention, preparedness and management of plant health outbreaks (e.g. of Citrus Black Spot, False Codling Moth, *Xylella fastidiosa*, *Spodoptera frugiperda*) remained a core part of the work in 2024 as DG SANTE continued the implementation of the [Plant Health Law](#). The [2023 Commission proposal for a targeted revision](#) of the latter, as part of the Commission's burden reduction initiative, was formally adopted by the Council on 18 November 2024. It will improve the way the EU fights plant pests, ensure that the plants that enter the EU are safe, and simplify procedures reducing the administrative burden for competent authorities by increasing the duration of their multiannual survey programmes. Increased digitalisation will also cut red tape for operators and national authorities alike.

The interim evaluation of the food chain strand of the Single Market Programme progressed under the lead of DG GROW and is to be finalised by end of January 2025.

The reports submitted by Member States on the implementation of the 25 phytosanitary programmes approved by the Commission in 2024 for a total amount of 8 million Euro, show that Member States take the necessary measures to survey and eradicate/contain quarantine pests in line with the plant health law.

Ensuring market access to safe substances and products. On 31 July 2024, the Commission adopted Commission Implementing Decisions and the related Commission Implementing Regulation [refusing the renewal of the authorisations for eight food smoke flavourings](#). After a phase-out period, these food flavourings will no longer be permitted for use in the EU. The Decisions are based on scientific assessments by the European Food Safety Authority (EFSA), which concluded that for all eight smoke flavourings assessed, genotoxicity concerns are either confirmed or cannot be ruled out.

Performing effective, efficient and reliable controls. During 2024, DG SANTE performed 143 Commission controls, including audits, in Member States (94 controls) and non-EU countries (49 controls) that export to the EU and issued recommendations in case of identified shortcomings. At the end of 2024, verified corrective actions had been taken by the Member States in response to 70 % of the audit recommendations addressed to them in the period 2020-2022 (see Annex 2, Result indicator 1.1.C). This is below the 2024 target of 80%. The indicator, which is based on a three-year rolling period, naturally oscillates at around 70%. To reach a closure of recommendations above 70%, Member States would need more time (a longer rolling period). DG SANTE continues to monitor all recommendations remaining open at the end of 2024 for progress and publishes the reports of the controls on its website. The DG also published overview reports summarising the situation in a certain sector based on the

controls carried out. In 2024, DG SANTE published three overview reports on: contingency plans (plant health), preparedness (plant health), animal-by-products. DG SANTE also published in 2024 an annual report on the official controls in the EU covering year 2022.

Maintaining rapid alert systems. In 2024, DG SANTE further worked on the adaptation of the rules governing the Information Management System for Official Controls (IMSOC). The project of a second generation Alert and Cooperation Network was pursued to provide better support to the network in managing day-to-day incidents as well as crises. In terms of rapid alert system for animal disease notification, DG SANTE made a significant step forward by enabling the bidirectional link between the Animal Disease Information System (ADIS) and the World Animal Health Information System (WAHIS), managed by the World Organisation for Animal Health (WOAH). This new iteration of ADIS aims to simplify data notification and reporting, improve data quality and accuracy, and facilitate data entry by the Competent Authorities. Since September 2024 a restricted number of Member States joined the ADIS pilot phase and are using ADIS as a single-entry point for both WOAH and EU notification legal requirements. This pilot phase will be expanded to more Member States and associated countries in 2025.

Specific Objective 1.2: Sustainable food systems – the ‘Farm to Fork’ Strategy

Following the launch in January 2024 of the Strategic Dialogue on the Future of EU Agriculture and the publication of [the report for a shared prospect for farming and food in Europe](#), DG SANTE is contributing to the preparation of the Vision for Agriculture and Food.

DG SANTE continued to coordinate the work (initiated by JRC in 2022) on the development of a framework for monitoring the sustainability of the EU food system and the progress achieved in various dimensions of food system sustainability, which resulted in a [dashboard of indicators](#), that was published in November 2024, together with a [technical report](#) explaining its development.

Reducing dependency on and promoting the sustainable use of pesticides. In May 2024 the Commission withdrew its [proposal for a Regulation on the Sustainable Use of Pesticides \(SUR\)](#) repealing the Sustainable Use of Pesticides Directive following its rejection by the European Parliament in November 2023. DG SANTE continued to work with and support Member States in the implementation of the current rules (the Sustainable Use of Pesticides Directive). Activities undertaken included Better Training for Safer Food (BTSF) training courses for national inspectors on Integrated Pest Management (IPM); the inspection of plant application equipment; and fit-for-purpose risk assessments of microorganisms used in plant protection products. The annual update on the [targets for reduction of pesticides](#) published in July showed, by the end of 2022, a reduction of the use and risk of chemical pesticides of 46% and a reduction of the use of more hazardous pesticides of 25% had been achieved at EU level from the baseline period of 2015-2017. Follow-up actions were undertaken in relation to open recommendations from previous audits to verify the corrective actions taken by Member States and audits concerning the application of the Directive and the authorisation, marketing and use of pesticides were also carried out in five Member States.

The Commission did not renew the approval of several chemical active substances as they were not fulfilling anymore the strict protection goals of the pesticides regulatory framework. To increase the ability of farmers to protect their crops with non-chemical alternatives, DG SANTE worked with Member States and EFSA to facilitate market access for biological control substance.



DG SANTE worked to facilitate the submission and evaluation of applications for approvals of micro-organisms - the main group of biological control substance pesticides – to ensure swift implementation of fit-for-purpose data requirements and assessment rules, as amended in 2022, by continuing the training of national experts (via the specific BTSF training scheme) to build expertise and by providing financial support to Member States via grants (see below) to recruit additional staff to conduct evaluations. DG SANTE also progressed with actions to facilitate approvals of low-risk chemical active substances. A revision of the guidance document on semiochemicals adopted in January 2024 provides for strongly reduced requirements to extend the list of approved pheromones. Furthermore, work on the update of the guidance document for baculovirus/bacteriophages advanced during 2024.

Improving the efficiency and effectiveness of the pesticide legislation. DG SANTE continued to implement actions to improve the efficiency of the existing legislative framework for pesticides as identified in the [evaluation](#) of 2020. In particular, in order to address the delays in completing safety assessments by the Member States DG SANTE made available financial grants from the Single Market Programme to increase the capacity of the relevant authorities (subject to certain conditions) to perform such work. Such agreements were signed with 11 Member States at the end of 2023 both for the areas of pesticides and biocides. DG SANTE also worked with Member States and ECHA to extend the duration of the review programme of existing biocidal active substances, and to agree on measures to improve its efficiency.



Reducing the use of antimicrobials in animals to contribute to the fight against antimicrobial resistance (AMR). DG SANTE continued to pursue the actions necessary to achieve the Farm to Fork target of reducing the overall EU sales of antimicrobials for farmed animals and aquaculture by 50% by 2030. From January 2023, all EU Member States, Norway and Iceland must report their data on the volume of sales and use of antimicrobial medicinal products in animals and submit their data to the [Antimicrobial Sales and Use \(ASU\) Platform](#) managed by EMA. Implementing rules for the new EU Regulations on Veterinary Medicinal Products and on Medicated Feed include core measures to combat AMR. These include restrictions on the use of certain antimicrobials³ in cases where those antimicrobials are used outside the terms of their marketing authorisation, and rules to ensure the effective and safe use of antimicrobials administered orally (via routes other than medicated feed) by the animal keeper to food-producing animals⁴. Particularly sensitive due to their potential impact on trade are the acts necessary for the implementation of the new measures for imports of animals and products of animal origin into the Union intended for human consumption, which includes the listing of authorised third [countries](#)⁵ and the amendment of the relevant official import certificates⁶. The Commission services continued to control the effective implementation of the Veterinary Medicinal Products Regulation, with focus on the prudent use of antimicrobials, with three audits on this topic. DG SANTE continued to control the correct implementation of the surveillance of AMR in the food chain for terrestrial farmed animals (bovines, pigs and poultry) and initiated discussions with Member States to develop a monitoring framework as regards AMR in aquaculture animals. In February 2024, the Commission adopted [a Delegated act](#) establishing specific maximum levels of cross-

³ Commission Implementing Regulation (EU) 2024/1973

⁴ Commission Delegated Regulation (EU) 2024/1159

⁵ Commission Implementing Regulation (EU) 2024/2598

⁶ Commission Implementing Regulation (EU) 2024/399 and Commission Implementing Regulation (EU) 2024/2020

contamination of antimicrobial active substances in non-target feed and methods of analysis for these substances in feed.

Fostering the use of innovative and more sustainable feedstuffs. The [evaluation of the Feed Additives legislation](#), Regulation (EC) No 1831/2003, published in February 2024 revealed that though the Regulation has worked well in general, there are potential areas for improvement, including aspects that have a simplification and burden reduction dimension including the better use of information and communication technologies (e.g. electronic means).

Reducing food loss and waste. DG SANTE continued its activities related to the EU's commitment to reaching the United Nations Sustainable Development Goal Target 12.3 of halving by 2030 the amount of food waste per capita at retail and consumer levels and reducing food losses along the food production and supply chains. In 2024, DG SANTE contributed to the negotiations between the Council and the Parliament on the [Commission's legislative proposal](#) – adopted in 2023 – to amend the Waste Framework Directive. The proposal introduces legally binding targets to reduce food waste across the EU, namely 10% in processing and manufacturing, and 30% (per capita), jointly at retail and consumption levels (restaurants, food services and households) by the end of 2030. Negotiations are expected to be completed in 2025.



DG SANTE continued operating the EU Platform on Food Losses and Food Waste to drive and reinforce action at national level, and in cooperation with ESTAT support Member States in the implementation of provisions on food waste measurement. With input from platform members, DG SANTE compiled in June 2024 a [mapping of voluntary agreements on food loss and waste reduction across Europe](#). It launched on 29 September 2024 the [“Zero Waste, More Taste”](#) campaign highlighting how reducing food waste in the home can be both easy and exciting creating also a recipe book featuring contributions from chefs representing each EU Member State. It showcases how leftover ingredients can be transformed into waste-free meals, with some of the recipes also turned into engaging videos. The campaign achieved significant engagement, reaching over 23 million users and generating 1.3 million link clicks and 7.7 million engagements outperforming the usual EU campaigns benchmarks. The video

ads were played 2.8 million times.

In May 2024, DG SANTE issued a call for proposals under the Single Market Programme for projects to reduce consumer food waste with a total budget of EUR 4 million to assist European stakeholders in addressing consumer food waste through various interventions such as behavioural changes, education and training, and communication materials. Another call for proposals has also been issued to support Member States in improving measurement of food waste and help implementing food waste prevention programmes with a total budget of EUR 2 million.

As households generate more than half of the total food waste (54%) in the EU, DG SANTE launched in July 2024 a consumer segmentation study on food waste prevention and datemarking. The study aims to generate consumer profiles at national, macroregional and EU level that can inform the design of effective consumer food waste prevention interventions, targeted and tailored towards those consumer profiles.

Ensuring a sustainable food production that improves the welfare of animals. To complement the Commission proposal on the welfare of dogs and cats adopted in December 2023, the Commission published in March 2024 a [Staff Working Document \(SWD\)](#) providing an summary of evidence of the commercial keeping, breeding and trade in cats and dogs in the EU, as well as their current traceability.

DG SANTE analysed the public feedback to the dogs and cats proposal and to the December 2023 Commission proposal on the welfare of animals during transport (5 500 feedback for transport and 500 feedback for dogs and cats), and published summaries of this analysis. Throughout 2024, the Commission has worked with the Council and the European Parliament as part of the ongoing ordinary legislative procedure on these two proposals. Important progress has been made with the adoption of a Council mandate for negotiating with the European Parliament on dogs and cats in June 2024. The Commission has presented and discussed the two proposals with various stakeholders, including third countries at the occasion of two side events (in the margin of the WOAHA General Assembly in May 2024 and in the margin of the FAO COAG meeting in July 2024).

At the end of 2024, the Commission launched two studies focusing mainly on the operationalisation of the digitalisation aspects of the respective legislative proposal, as well as of the rules on breeding in the case of dogs and cats.

In May 2024, DG SANTE established an Animal Welfare Expert Group and an Animal Welfare Working Group with Member States. These groups shall allow for an exchange between the Commission and the Member States on practical matters related to animal welfare, as well as the preparation of tertiary legislation. First meetings were held on 16 September 2024. Furthermore, DG SANTE's management of the EU Animal Welfare Platform allowed for updates on the strategic dialogue on the future of agriculture and food, on the work of EFSA and the EU Animal Welfare Reference Centres, on animal welfare trainings under BTSF and on various research projects financed under Horizon 2020. A subgroup on policy indicators for animal welfare created under the Platform held two meetings in 2024. The Commission

launched a study on this topic as well.

In 2024, DG SANTE designated a new Reference Centre for the welfare of aquatic animals and supervised the work of the four Animal Welfare Reference Centres. In 2024, the EU pilot project “Care4Dairy” was finalised making available factsheets, best practice guides, podcasts, videos and self-assessment tools to improve dairy farm management. In October 2024, under the Administrative Assistance and Cooperation Network, the Animal Welfare Network (AWN) was established, operating on the iRASFF online platform. The AWN will enhance collaboration and information sharing among EU Member State authorities on animal welfare thus facilitating cross-border support in case of non-compliances.

Fighting against agri-food fraud. DG SANTE continued to provide Member States with intelligence on agri-food fraud matters and launched new coordinated actions with the EU Food Fraud Network and relevant Commission services. On 29 February, the [first monthly report on agri-food fraud suspicions](#) was published and all communication channels were used to boost its visibility. The report compiles information from the Alert and Cooperation Network (ACN) and includes cases of cross-border non-compliance.



Empowering consumers to make informed food choices through the provision of food information. In 2024, DG SANTE continued to work on the implementation of the existing food information rules, including through the assessment of national notifications and authorisation of health claims on food products following the latest scientific assessments from EFSA. Work continued on the maximum amounts of vitamins and minerals that can be added to foods, including food supplements and on the implementation of the Regulation on Food for specific groups (food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control).

DG SANTE continued the work on the development of criteria for Sustainable Public Procurement (SPP) of food and catering services. Schools, hospitals and public institutions relying on SPP criteria to source sustainable food and catering services can

accelerate the transition towards sustainable food systems. The SPP criteria are being developed with scientific support of the Joint Research Centre (JRC). As a first task, the JRC published a report with an overview and analysis of existing criteria, tools and guidelines that are currently used in the Member States. This overview and analysis will form a basis for the JRC to propose a set of possible criteria for sustainable public food procurement.

Supporting innovation in the food chain, especially via the promotion of novel food, plant reproductive materials and innovative techniques. DG SANTE authorised 13 novel foods in 2024, in addition to 9 amendments of the conditions of use and specifications of already authorised novel foods. Upon request by DG SANTE, EFSA updated its [technical guidance for the preparation and submission of novel food applications](#) (published on 3 October 2024) and launched a [Call for Expression of Interest](#) (EOI) to raise awareness and facilitate access for Small and Medium-Sized (SME) applicants to the general pre-submission advice (GPSA) service, specifically in the area of novel foods. Following the adoption of the [Commission's Communication on Biotechnology and Biomanufacturing](#), DG SANTE joined DG GROW and DG RTD to launch a study that will explore possibilities to simplify and streamline the regulatory framework applicable to biotech innovations in a broad range of sectors, including medical and pharmaceutical, agrifood, industrial, environmental, and marine sectors. The outcome of the study will be considered in the preparation of a European Biotech Act.

DG SANTE supported the work of the co-legislators in examining the Commission's proposals for a [Regulation on plant reproductive material](#) and a [Regulation on forest reproductive material](#), which aim to modernise the legal framework for these sectors. The European Parliament adopted its mandates for the negotiations on both files in April 2024. Work to evaluate the [EU legislation on plant variety rights](#) which aims to stimulate the continued breeding of improved varieties through the grant of intellectual property rights valid throughout the EU has started. The evaluation will also cover the Community Plant Variety Office (CPVO) managing these rights.

Improving the regulatory framework on Food Contact Materials (FCM). DG SANTE continued its preparatory work for an impact assessment supporting the revision of the FCM legislative framework. In April 2024, the report of a study commissioned by DG SANTE concerning information exchange, compliance and enforcement was finalised and a [study on the possible inclusion of sustainability aspects in the future FCM legislative framework](#) was launched. Following an EFSA opinion indicating that bisphenol A (BPA) has potential harmful effects on the immune system, and after the endorsement by Member States, the Commission banned its use in December 2024 as well as the use of other hazardous bisphenols in FCM. The BPA ban will apply to the vast majority of FCM, such as the coating used on metal cans, and consumer articles such as kitchen utensils, tableware, plastic drink bottles, and water distribution coolers. For most products, there will be an 18-month phase out period, with some products subject to a 36 month phase-out period, to allow industry time to fully adapt and avoid disruption in the food chain. Member states also endorsed amendments to certain technical rules to improve the quality of plastic FCM to be adopted by the Commission early 2025.

DG SANTE continued implementing the regulation on recycling of plastic food contact materials adopted in 2022. This included preparing, decisions for more than 300 authorisations of mechanical PET plastic recycling processes. The first 51 Decisions were endorsed with unanimity by the Member States by the end of 2024. DG SANTE registered 764 Recycling installations, both in the EU and globally. This will facilitate the uptake of recycled plastics by the food packaging industry, which accounts for a major part of plastic packaging and will represent a significant contribution to the Circular Economy Action Plan.

Specific Objective 1.3: International promotion of EU food safety standards

Improving multilateral relations. In 2024, DG SANTE continued to promote food safety and quality standards and the global transition to sustainable food systems, including through the BTSF programme and the Commission's Foreign Policy and Trade Initiatives, through its work in multilateral fora and international standard setting bodies.

In the context of the World Trade Organization (WTO), DG SANTE represented the EU in the Sanitary and Phytosanitary (SPS) Committee meetings where it continued to promote sustainability and the One Health approach, particularly during the ongoing 6th Review of the Operation and Implementation of the SPS Agreement. DG SANTE co-organised thematic sessions and initiated information sharing events on a number of topics (e.g. emerging risks, use of digital tools in the SPS field, BTSF, Agrinfo). The DG also continued its work in the context of the WTO Committee on Technical Barriers to Trade (TBT) in certain policy areas, such as food labelling, halal meat and animal welfare.

In particular, in the World Organisation for Animal Health (WOAH), DG SANTE defends the EU's high animal health and welfare standards and works to influence and promote international standards. In particular, the EU's active engagement during the 91st General Session in Paris allowed:

- To strengthen EU leadership in WOAH with Emmanuelle Soubeyran (FR) elected as Director General, Susana Pombo (PT) as Council President, all European Regional Commission members re-elected, and 7 Europeans elected to WOAH Specialist Commissions.
- to foster collaboration on high pathogenicity avian influenza (HPAI) prevention and control, where the EU shared insights on vaccination strategies and surveillance;
- the EU to showcase its legislative advancements in animal welfare and initiating constructive dialogues with third countries, for instance by contributing to the revision of the WOAH standards on transport and on welfare at the time of killing.
- Successful participation of the EU in WOAH standard setting (all objectives reached), with EU CVOs speaking with one voice "on behalf of the 27 EU MSs" on several topics (animal health, zoonoses, animal welfare, information systems).

DG SANTE represented the EU within the Codex Alimentarius and contributed to the development of international standards, leading on priority matters to promote food safety at global level. The DG steered alignment between EU legislation and Codex standards, as much as possible, and continued to advocate for the inclusion of the One Health approach

and sustainability aspects in the 2026-2031 Codex Strategic Plan.

Within the multilateral fora of UN, FAO and WHO, SANTE continued to advocate and strengthen a One Health approach, sustainability aspects, and the promotion of prudent and responsible use of antimicrobials. As a follow up to the UN Food Systems Summit +2 Stocktaking Moment, it has participated in debates on sustainability, resilient food systems and healthy diets.

DG SANTE actively participated and contributed to the Convention on Biological Diversity (CBD) and the Cartagena Protocol (CP) on Biosafety. The 16th Conference of the Parties to the CBD/11th Meeting of the Parties to the CP (COP 16/MOP 11) took place in Cali, Colombia. DG SANTE contributed to the development of coordinated EU positions and participated in the negotiations during these meetings which resulted in the adoption of several decisions on matters concerning biosafety compliance, risk assessment and management, detection and synthetic biology.



DG SANTE continued to coordinate EU positions within the International Plant Protection Convention (IPPC) and contributed actively to the work of IPPC in priority area to promote food safety at the international level and to ensure that EU legislation and the International Standards for Phytosanitary Measures (ISPMs) are well aligned. For example, DG SANTE coordinated the EU's position on the first draft commodity standard on Mango fruits which will be proposed for adoption in 2025, provided technical information for the development of commodity standards on Citrus fruits and bean seeds, as well as provided financial support on the development of EU priority topics such as Commodity standards and Pest Outbreak Alert and Response System (POARS).

DG SANTE continued its collaboration with the European and Mediterranean Plant Protection Organization (EPPO) through active participation in the different EPPO panels to contribute

to the development of high-quality regional standards for phytosanitary measures and ensure the EU legislation and those standards are well aligned. DG SANTE also coordinated the EU's position for the election of the new EPPO Director General. DG SANTE also contracted EPPO to perform an evaluation of the Regulated non-quarantine Pests (RNQPs) from the EU fruit Marketing Directive and the measures against those RNQPs to promote food safety.

In 2024 DG SANTE continued to coordinate the EU positions within OECD in relation to the OECD Seed Schemes and the OECD Forest Seed and Plant Scheme and within UPOV in relation to the International Convention for the Protection of New Varieties of Plants and actively participated in the relevant meetings, thus contributed to the further development of those international standards. DG SANTE also contributed to the intersessional work under the International Treaty on Plant Genetic Resources (ITPGRFA).

Improving bilateral trade relations. DG SANTE concluded in March 2024 the negotiation of the Sustainable Food system ("SFS") Chapter with India in the framework of the on-going bilateral trade agreement negotiations. A SFS chapter was included in the trade negotiations with Thailand and the Philippines and negotiations proceeded very well in many articles.

In July 2024, South Korea recognised EU regionalisation for African Swine Fever and High pathogenic Avian Influenza, which led to the export of pork and poultry products from some EU Member States to South Korea. In December 2024, DG SANTE concluded with the South Korean Ministry of Food and Drug Safety three types of harmonized electronic health certificates for sterilized meat products, dairy products and processed egg products respectively.

Negotiations with a view to include new agreements with Switzerland on health (health security & participation in EU4Health), on food safety, as well as on institutional and substantive changes to Annexes of the MRA relevant for health and food safety (medical devices, medicines and biocides) were finalised at the end of December. After the new agreements come into force, Switzerland will have the right to take part in relevant EU mechanisms, systems and bodies (*i.a.* ECDC, EWRS and EFSA) and will dynamically align with EU rules covering all dimensions of the food chain and health security.

DG SANTE continued engagement with the UK in the framework of the implementation of the EU-UK Trade and Cooperation Agreement in the areas of sanitary and phytosanitary measures and pharmaceuticals at technical level.

Enlargement and more focused neighborhood policies are priorities for the Commission. Following the start of the accession negotiations with Ukraine and Moldova, DG SANTE shared questionnaires on health and food safety to prepare the screening process in 2025. Furthermore, enlargement talks progressed with Montenegro as well as with Albania on health and food safety.

DG SANTE continued to support trade facilitation from and to Ukraine under the Solidarity Lanes provisions and to manage the relations with Turkey, the Eastern and Southern Partnership and the Africa Strategy on food matters.

General Objective 2: PROMOTING OUR EUROPEAN WAY OF LIFE

European Health Union. In May 2024, the Commission presented a [Communication on the European health Union](#) highlighting significant strides in the EU health policy over the last four years.

Implementation and simplification of the existing regulatory framework was pursued whenever possible – as an example, changes to the Variation framework for human medicinal products⁷ as an action under the Pharmaceutical strategy for Europe (i.e. changes to a marketing authorisation after the initial authorisation simpler, clearer and more flexible to allow for a streamlined product life cycle management embracing technical developments and efficient regulatory processes). Rationalisation of reporting obligations, in particular for national authorities in the Member States, related to the gradual roll out of various modules of the European database on medical devices (Eudamed). For more information on simplification initiatives (see Annex 2, Result Indicators 2.1.D and 2.1.E).

Non-communicable diseases. In the area of non-communicable diseases, the '[Healthier Together](#)' initiative, co-created with Member States and stakeholders, provides the strategic framework to support Member States in tackling non-communicable diseases, including cardiovascular diseases. The Commission supports knowledge sharing, such as the exchange of [best practices](#) between the Member States, and activities to improve health literacy. Financial support is provided under the EU4Health programme, for example, the Joint Action JACARDI with funding of EUR 53 million supports Member States in reducing the burden of cardiovascular diseases, diabetes and associated risk factors, both at the individual and societal levels. The Joint Action PreventNCD, with funding of EUR 76 million aims to assist Member States in addressing health determinants and common risk factors for non-communicable diseases.

Long COVID. In response to the pressing issue of Long COVID, the [Network of Expertise on Long COVID](#) was established in 2023 under the supervision of the Public Health Expert Group (PHEG) of DG SANTE. The network brings together national institutions from 21 Member States and Iceland with the aim to promote international collaboration and strengthen EU and national-level responses to Long COVID.

The EU4Health project on Long COVID was launched, with a financial support of EUR 2 million, with 7 initiatives to be implemented in collaboration with the OECD (EUR 1.5 million) and WHO (EUR 0.5 million) to address important aspects of Long COVID.

Support to Ukraine. DG SANTE continued to participate in the Commission's efforts to coordinate with other International Organisations, non-governmental organisations and health professionals and patients' associations, in order to mobilise resources and help both patients inside Ukraine and people coming into the EU from Ukraine. DG SANTE worked with

⁷ Commission Delegated Regulation (EU) 2024/1701 of 11 March 2024 amending Regulation (EC) No 1234/2008 as regards examination of variations to the terms of marketing authorisations for medicinal products for human use.

health ministries through the EU Health Security Committee. The European system for swift medical evacuation of patients in need to EU Member States continued and a specific module to support patients' confidential data transfer is now available in the Early Warning and Response System. The Ukrainian Ministry of Health participates in the Joint Action on the Integration of ERNs into National Healthcare Systems as an Associated Partner, allowing Ukraine to follow all developments of the Joint Action and access all its deliverables. An Administrative Arrangement has been signed which will make it easier for Ukrainian healthcare providers to seek advice on Ukrainian rare or complex disease patients from members of the European Reference Networks.

The Commission has mobilised to date over EUR 30 million from the EU4Health programme to help people fleeing Ukraine in urgent need of mental health and trauma support. Mental health support to displaced people from Ukraine is being carried out via (1) contribution agreement of EUR 31.2 million with the International Federation of Red Cross and Red Crescent Societies; and (2) four projects to implement best practices on improving mental health and psychosocial well-being. The Communication on a comprehensive approach to mental health specifically addresses vulnerable groups, such as children and young people including displaced people from Ukraine. Through the EU-PROMENS project the Commission strengthens the multidisciplinary training of healthcare professionals, such as psychiatrists, and other professionals, such as teachers and social workers, on mental health across the EU countries, as well as in Ukraine.

Conflict in the Middle East: On 24 July 2024, the first EU-coordinated medical evacuation operation of 16 Palestinian children and their family members took place from Egypt to Spain. The operation was financially and operationally supported by the EU Civil Protection Mechanism (UCPM), in close coordination with the World Health Organization (WHO), the Palestine Children's Relief Fund (PCRF) and authorities of all countries involved. DG SANTE continues to support DG ECHO in this operation, e.g. with joint meetings between civil protection authorities and the Health Security Committee.

Comprehensive initiative on mental health. The Commission communication on a comprehensive approach to mental health with 20 flagship initiatives and EUR 1.23 billion in funding opportunities continued to be implemented. On the occasion of World Mental Health Day (10 October) 1) an updated [tracking framework](#) was published, showing that all 20 initiatives are ongoing or completed, and 2) an EU support package on stigma surrounding mental health presented, including the #InThisTogether campaign. A new three-year Joint Action 'Mental Health Together' (EUR 6 million) started in October 2024 supporting Member States in the implementation of the Communication. The communication campaign "In this Together" on tackling stigma around mental health, and aiming particularly at young people, included influencers and testimonials, teaching materials, and a new web-hub among others.

World Mental Health Day



The project EU PROMENS, launched in January 2024 with an investment of EUR 9 million, provides multidisciplinary training for health professionals and other professionals, such as teachers, social workers and prison officials, in 30 participating countries, including Ukraine. In addition, an exchange programme will support knowledge sharing for around 1000 mental health professionals in 6 hubs across the EU. The first set of exchange visits focused on meeting the challenges of today with a multidisciplinary approach to mental health, and the prevention, crisis resolution, treatment and recovery-oriented practices in an ecosystem of mental health.

A three-year project of EUR 2 million for a Children Health 360 prevention toolkit (Flagship 'Children Health 360' of Communication on a comprehensive approach to mental health), with support from UNICEF was launched in December 2024 to support activities that address the links between mental and physical health in children and young people.

EU funding for health. Supported by the European Health and Digital Executive Agency (HaDEA), DG SANTE continued to monitor the implementation of the [EU4Health annual work programmes](#) 2021, 2022, 2023 and 2024. The Commission adopted the fourth annual work programme for 2024 as amended on 15 November 2024 with a budget of EUR 752.4 million. Work on the interim evaluation of the programme progressed. DG SANTE developed a sound performance and evaluation framework in view of monitoring the EU4Health Programme's performance and to deliver its interim and final review. Data collection is coordinated by the parent DGs and enabled by Programme and action level indicators designed according to the RACER criteria. Based on DG SANTE's checks and verifications, in accordance with the relevant corporate criteria, all performance information is considered reliable.

On 19 July 2024, the Commission signed an association agreement to the EU4Health Programme with Montenegro and on 23 July 2024 with Bosnia and Herzegovina. The other

countries associated to the EU4Health Programme are Norway, Iceland, Ukraine, and Moldova.

DG SANTE's work in the field of health is supported by the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and the Scientific Committee on Consumer Safety (SCCS).

Specific Objective 2.1: Diminishing the impact of cancer in Europe

Europe's Beating Cancer Plan. As a key delivery of [Europe's Beating Cancer Plan](#), the Commission presented in January 2024 a [proposal for a Council Recommendation on vaccine-preventable cancers](#) to support Member States in their efforts to prevent cancer through vaccination. EU Health Ministers adopted the [Recommendation](#) in June 2024. It calls on Member States to boost the uptake of vaccination against Human papillomaviruses (HPV) and Hepatitis B virus (HBV) that can lead to cancer. It calls on Member States to improve the monitoring of vaccination coverage rates to inform targeted public health action in the field. It will be implemented through an EUR 20 million joint action under the EU4Health 2024 Work Programme. Communication campaigns were run to promote the uptake of the HBV and HPV vaccines, targeting the appropriate demographics via social media, influencers, multiplier organisations and traditional communication channels. The EU4Health programme continued to provide significant financial support to Member States in their efforts to boost vaccination and combat cancer. The Joint Action PERCH, running from November 2022 to April 2025, is developing communication strategies to support Member States in launching national HPV vaccination actions and campaigns, and promoting the inclusion of HPV into national routine vaccination schedules. It is updating knowledge on the efficacy and safety of HPV vaccines, identifying strategies to purchase them at the lowest possible cost, and improving the data collection and monitoring of vaccination coverage.

In October a [study](#) was published mapping policies and good practices in the EU and EEA/EFTA that help cancer patients and those with a history of cancer to remain in and return to work.

Together with DG FISMA, DG SANTE continued its efforts in view of publishing a Code of Conduct, a stakeholder-led document, on addressing fair access for cancer survivors to financial services. Insurance companies and cancer community made important progress on the topic and shared the output of their work at a conference on 14 May 2024. A report summarising the work funded by the EU4Health program to support this initiative was published in November 2024.

Building on the work of Joint Action Jane, which laid the foundations of 7 Networks of Expertise on cancer-related issues, and the Joint Action Crane, which established standards and criteria of the first EU network of comprehensive Cancer Centers, two follow up Joint Actions were launched in October 2024 to implement the activities of the networks. Another Joint Action with Member States started in June 2024 to support the full implementation of

cancer screening for breast, colorectal and cervical cancers, and test the feasibility of cancer screening for prostate, lung and gastric cancers to facilitate a stepwise approach for roll-out and full implementation.

The European guidelines and quality assurance schemes for these cancers were being developed. The first [European quality assurance scheme for breast cancer services](#) has been endorsed by the European Co-operation for Accreditation in November 2024 and was published in February 2025. The #GetScreenedEU campaign in Belgium, Malta, Cyprus, Estonia and Latvia reached over 40 million people and will be launched in Greece, Romania and Poland in 2025.

A large-scale event for World Cancer Day in February 2024 took stock of the progress and impact of Europe's Beating Cancer Plan to date.

Tobacco control. In [Europe's Beating Cancer Plan](#), the Commission set the goal of achieving a tobacco-free generation by 2040 where 5 % of the EU population uses tobacco products compared to 25 % in 2021.

The Council adopted the updated 2009 Council recommendation on smoke-free environments on 3 December 2024. It calls on Member States to extend smoke-free policies to key outdoor areas, to better protect people in the EU, particularly children and young people, to extend smoke- and aerosol-free policies to emerging products such as heated tobacco products and electronic cigarettes, which increasingly reach very young users. The Commission will support Member States (including through a direct grant worth €16 million from the EU4Health programme and €80 million from the Horizon programme) to better protect citizens from harmful exposure to smoke and aerosols, as well as to de-normalise the use of traditional tobacco and emerging products such as electronic cigarettes and heated tobacco products.

On 20 May 2024, the EU tobacco traceability system was extended to include all tobacco products other than cigarettes and roll-your-own tobacco. All tobacco products are now covered by the traceability system. This is a substantial improvement to the capacity of the tobacco regulators and public authorities and will result in: (a) detecting potential fraud cases in the illicit trade of all tobacco products and eventually reducing the availability of their illicit supplies (b) an increase in budget revenues from the taxes on these products (c) enhancing public health protection by reducing artificially cheap supplies of illegal tobacco products affecting the uptake and general prevalence of tobacco consumption.



The Commission continued to monitor the transposition of the Delegated Directive (EU) 2022/2100 on heated tobacco products into the national law of the Member States⁸.

In February 2024, DG SANTE ensured strong and coordinated EU participation at the 10th session of the Conference of the Parties (COP10) to the WHO Framework Convention on Tobacco Control (FCTC). COP10 achieved important advances in tobacco control with the adoption of a decision on the protection of environment from impacts of tobacco products, and the adoption of specific guidelines on cross-border tobacco advertising, promotion and sponsorship and the depiction of tobacco in the entertainment media.

Specific Objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices

Pharmaceutical Strategy for Europe. DG SANTE continued to implement of the Pharmaceutical Strategy for Europe, a patient-centered strategy that aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness. Inter-institutional negotiations continued on the reform of the pharmaceutical legal framework, including medicines for children and rare diseases. This reform is a comprehensive review of the current framework to make it more agile, flexible, and adapted to the needs of citizens and businesses across the EU. Actions in 2024 were supported by communication actions on traditional and social media.

Preparations began for the Critical Medicines Act, which will complement the reform of the EU's pharmaceutical legislation as proposed by the Commission. It will aim to reduce

⁸ The Delegated Directive, applicable in the Member States from 23 October 2023, strengthens tobacco control measures by prohibiting the placement on the market of heated tobacco products with a characterising flavour or flavourings in any of their components and by setting stricter labelling requirements for heated tobacco products for smoking.

dependencies primarily in the area of critical medicines and ingredients, particularly for products supplied by only a few manufacturers or countries. It will also introduce actions to improve access to and availability of other medicines of common interest.

As part of the follow-up actions to the Communication on shortages of medicines and to the Staff Working Document on security of supply, a second version of the Union List of Critical Medicines was published. The Voluntary Solidarity Mechanism, that was established following the Communication, was triggered several times during 2024 and proved to be successful for Member States requiring support.

Implementation and application of the pharmaceutical legislation. Of the 100 new medicines authorised for human use in 2024, 38 included a new active substance, and 17 were authorised for treatment of rare diseases of which 2 are advanced therapy medicines). The Commission adopted 1,094 decisions amending marketing authorisations for medicinal products for human use and 140 new designations for orphan medicines. As to the result indicator '2.2.A: Access to centrally authorised medicines for unmet needs', 25 new authorisations were granted (see Annex 2). As regards veterinary medicines, in 2024, there were 22 new veterinary medicines authorised at EU-level.

A [delegated Regulation](#) was adopted by the Commission on 11 March revising the rules setting out the procedures for post-authorisation changes to a marketing authorisation for medicines for human use. It aims at making the post-marketing lifecycle management of medicines more efficient, by reducing the administrative burden for the pharmaceutical industry and making better use of regulatory authorities' resources. In July 2024, a [report](#) by the Commission revealed that overall substantial and steady progress in detecting falsified medicines has been observed since the [Falsified Medicines Directive](#) and the [Delegated Regulation](#) came into application.

In 2024, DG SANTE continued monitoring the implementation of the Clinical Trials Regulation with all initial clinical trial applications in the EU being required to be submitted via the Clinical Trials Information System (CTIS) since January 2023. CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. Following the entry into force of the [revised CTIS transparency rules](#), a new version of CTIS was launched in June 2024 allowing earlier and more efficient access to information about clinical trials in the EU for patients, healthcare professionals and other stakeholders with approximately 4,000 clinical trials with issued decisions now publicly accessible. In June 2024, two new advice pilots to improve clinical trials in Europe were launched under the Accelerating Clinical Trials in the EU (ACT EU) aimed at improving the quality of applications for clinical trials. Sponsors of clinical trials were reminded to transition to the new system by end-January 2025 through boosted communication. Union controls, focusing on the prior authorisation of clinical trials, of the 27 Member States (plus Norway and Ireland) were completed in the form of e-surveys.

Clinical Trials: transition to the new Clinical Trials Regulation

#HealthUnion



In February 2024, the European Parliament and the Council adopted a new Regulation on fees charged by the European Medicines Agency (EMA). Following adoption, DG SANTE has been working closely with the Agency on the preparation of a set of working arrangements to facilitate the technical implementation of the Regulation. This included the establishment of specific fee reductions as well as of a common format for the submission of financial information as part of the new monitoring system set up in the act. The new fee Regulation became applicable on 1 January 2025.

International cooperation in the area of pharmaceuticals. DG SANTE continued to exercise leadership in several multilateral fora, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Coalition of Medicines Regulatory Authorities (ICMRA), advancing global harmonisation and regulatory convergence. In May 2024, the EU's commitment to regulatory excellence was recognised through the designation of the European Medicines Regulatory Network (EMRN) as WHO Listed Authority (WLA) by the World Health Organization (WHO). The EMRN was recognised as a 'single entity' and becomes the first "Regional Regulatory System" to be listed as a WLA. This is a remarkable achievement for the Network and a global recognition of the EU's commitment to regulatory excellence.

DG SANTE, EFSA and EMA held their biennial meeting with the US Food and Drug Administration (FDA), to allow the strategic partners to review their ongoing initiatives, exchange strategic priorities, strengthen existing collaborations, and explore new opportunities. Both the EU and US sides reiterated their determination to complete the process of recognition of Member States' veterinary medicines authorities as soon as possible. In 2024, the capability assessment of EU veterinary competent authorities by the US FDA under the Guidelines for Good Manufacturing Practices Annex to the EU-US Mutual Recognition Agreement progressed with a total of 24 Member States now recognised. On the basis of the Commission [assessment](#) of the written guarantees provided by the United Kingdom, Regulation (EU) 2023/1182 became applicable as of 1 January 2025, introducing

specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland.

Health Technology Assessment (HTA) The [new HTA Regulation](#) which applies from 12 January 2025, established a legal framework for cooperation of Member States on the clinical assessment of medicinal products and medical devices at Union level. In preparation for its application in January 2025 four [implementing acts were adopted in 2024](#): The first act was adopted on 23 May covering [new rules for the joint clinical assessments of medicines at Union level](#). These new rules define the timelines and the steps for conducting EU joint clinical assessments. The 2nd act was adopted on 18 October setting [rules for cooperation with the European Medicines Agency](#). These define the information to be shared for (1) planning and forecasting of joint clinical assessments and joint scientific consultations (2) for identifying patients, clinical experts and other relevant experts to be involved in these joint procedures; and (3) on general scientific and technical matters related to health technology assessment. The 3rd act was adopted on 25 October covering [rules for managing conflicts of interest](#) of those involved in joint clinical assessments and joint scientific consultations. These rules aim to ensure that EU-level assessments of new health technologies are conducted in an independent, impartial and transparent manner, free from conflicts of interest. The 4th act was adopted on 18 December and concerns [rules for carrying out joint scientific consultations on medicinal products](#). These consultations will occur during the development of the medicinal product and they are voluntary and free of charge for pharmaceutical companies. A fifth Implementing Act on joint scientific consultations on medical devices and in vitro diagnostic medical devices was adopted on 24 January 2025. A sixth and final foreseen implementing act focusing on joint clinical assessments for medical devices is in preparation. In addition, four regional HTA information and awareness raising events in Member States took place in collaboration with the Heads of HTA agencies group. The development of the dedicated secure IT Platform to facilitate the joint work foreseen in 2025 was enhanced.

Medical Devices and In Vitro Diagnostic Medical Devices. In 2024, the Commission launched a targeted evaluation of EU medical device legislation to assess, among other aspects, the impacts of the two Regulations on the availability of medical devices in the EU, in particular orphan devices and innovative devices and as well as the costs and administrative burden stemming from the implementation of the legislation, especially for micro and SMEs.



In June 2024, the [amending Regulation](#) to the medical device Regulation set measures to improve the availability of in vitro diagnostics (IVDs) for patients and healthcare providers, by granting more time to companies to transition to the EU rules on IVDs. The amending Regulation has also introduced a new obligation on manufacturers to inform national authorities and the health sector in case of disruption of supply of certain medical devices and allows for the gradual roll-out of the European Database on Medical Devices (Eudamed). In June 2024, guidance on the clinical evaluation of orphan medical devices was published.

Specific Objective 2.3: Effective response coordination of serious cross-border health threats

Health security preparedness and response. DG SANTE is the key EU actor piloting EU health security policy, drawing on the essential recent Regulation on serious cross-border threats to health, including on the substantially upgraded Health Security Committee with key additional responsibilities in that EU law. DG pursued its strategic work on the implementation of the Regulation and started work on its evaluation as per legal provisions. In May 2024, the Commission Delegated Regulation defining the procedures, standards, and criteria for the assessments of Member States' prevention, preparedness, and response plans was adopted. During 2024, in total seven country assessments were conducted under the leadership of the European Centre for Disease Prevention and Control (ECDC). The first report on EU/EEA countries' prevention, preparedness, and response planning was shared with the Health Security Committee for discussion in October 2024. The aggregated report summarised information provided by the countries by 27 December 2023 and includes country profiles.

To implement Article 11 of the Regulation that calls for trainings, SANTE works with an external contractor (the Emergency Preparedness Integrated Courses consortium (EPIC11)). In 2024 a series of workshops and exchange visits were organised in several Member States

with the objective of assessing training needs based on which the general EU health security preparedness training programme is developed. DG SANTE, supported by an external contractor, also worked on the evaluation of the Regulation to map the first two years of implementation of the Regulation and assess the process from the better regulation perspective.

The Joint Procurement Agreement for medical countermeasures against serious cross-border health threats was paramount in fighting the COVID-19 pandemic. An assessment of the JPA mechanism was completed in 2023 looking at how joint procurement has worked in practice, both before and during the COVID-19 pandemic. The report will be published in Q2/2025.

In July 2024, Moldova became the 38th country to sign the Joint Procurement Agreement for medical countermeasures against serious cross-border health threats.

On the 14 August, the WHO declared Mpox as a global health emergency of international concern due to outbreaks in the Democratic Republic of Congo (DRC) and other African countries. This situation highlighted the urgent need for a coordinated global response to contain the virus and protect public health. DG SANTE led the coordination, also through the Health Security Committee in order to ensure that the EU and its Member States (“Team Europe”) provided immediate and comprehensive action to help partners control and respond to the Mpox outbreak, covering the many relevant areas necessary for an effective response.

Climate change increases the risk of zoonoses, food- and water-borne and vector-borne diseases, with the presence of invasive species of mosquitos expanding geographically. A recent report by ECDC confirmed the presence of the *Aedes albopictus* mosquito in 13 EU/EEA countries and the *Aedes aegypti* mosquito recently established in Cyprus, which can contribute to the spread of Chikungunya, Zika, dengue and yellow fever. A contribution agreement has been signed with the International Nuclear Energy Agency (IAEA) in 2024 to establish capacity to use the Sterile Insect Technique as a tool to eliminate *Aedes aegypti* in Cyprus and potentially in other EU countries if detected. The list of diseases and events under surveillance at EU level is under revision along with the surveillance standards and the definition of the technical terms of the IT surveillance platform. Several informal consultations to gather input for the draft legal acts have taken place, e.g. with the Health Security Committee and its thematic working groups. In 2024, the European Climate and Health Observatory was equipped with additional budget to support efforts in generating and pooling knowledge on the links between climate change and health, with a specific focus on vector-borne diseases and capacity building on the ground.

The EU4Health programme supports Member States to improve their national surveillance of communicable diseases. Direct grants have been signed in 2024 with 23 countries to close national gaps in surveillance systems, to digitalise surveillance systems, and to build capacity for surveillance, such as in personal data protection and data quality assurance.

In 2024, the Commission has started designating European Reference Laboratories (EURLs) for public health that further strengthen the EU’s preparedness, and response to serious

cross-border threats to health. The EURLs bring together scientific expertise from across the European Union, to improve preparedness, rapid detection, and response. EURLs will support national public health laboratories by ensuring data comparability and capacity strengthening on laboratory methods at the EU level. The first six EURLs were designated in March 2024 and cover the following areas: Antimicrobial resistance (AMR) in bacteria, Vector-borne viral pathogens, Emerging, rodent-borne and zoonotic viral pathogens, High-risk, emerging and zoonotic bacterial pathogens, Legionella, Diphtheria and pertussis. In November 2024, three more EURLs were designated, covering food- and water-borne viruses, food- and water-borne bacteria and food-, vector- and water-borne helminths and parasites.

Civil-military cooperation on health security. The Russia's aggression against Ukraine requires collective civil-military efforts in the EU, including increased preparedness and resilience of the civil health sector. The support of the civil health sector to military operations is crucial in case of a potential large-scale armed conflict/large-scale combat operation (LSCO) affecting the EU territory, in terms of capacities of the healthcare system, including medical evacuations, hospital beds, properly skilled health workforce, supply of medical devices, medicines, blood, and medical countermeasures to CBRN threats.

Recognizing this, based on discussions of, and broadly supported by, the Health Security Committee the establishment of a Technical Working Group on Civil-Military Cooperation on Health is on its way. In the same spirit, regular contacts have been established in 2024 with the NATO Joint Health Group.

DG SANTE participated in the CAMO24 (Casualty Move) exercise in September 2024, involving 14 EU MS, the US and Norway, which provided an opportunity for civil-military cooperation on health security and testing the draft NATO patient flow management guideline, involving SANTE's Early Warning and Response System.

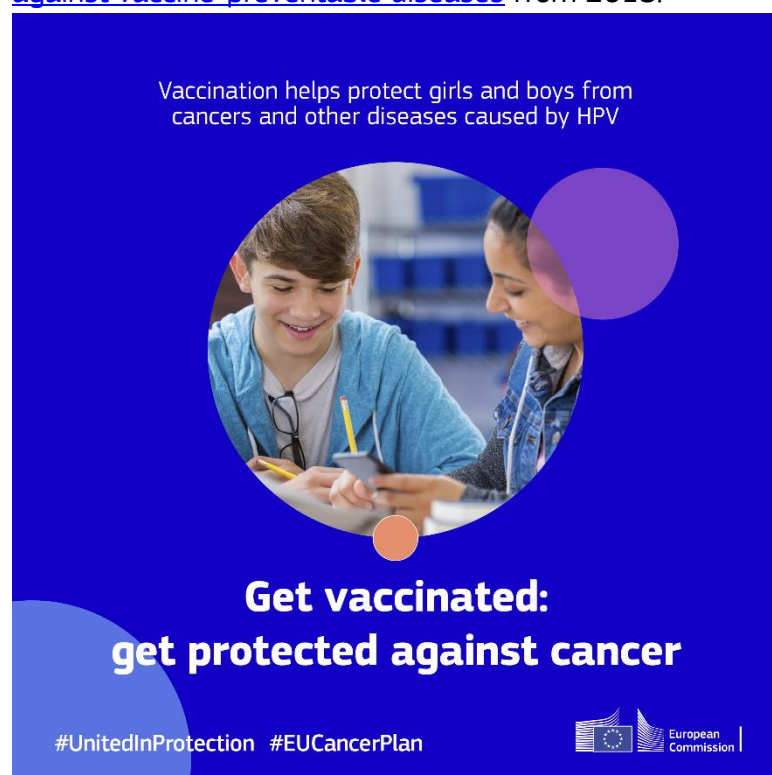
DG SANTE participated in the EU-NATO Parallel and Coordinated Exercise (PACE24) in October 2024 organised by DG ECHO with several other Commission services – 15+ DGs, several EU agencies, other EU bodies and the majority of EU MSs - involved; DG SANTE was leading the sub-scenario describing several public health emergencies overwhelming the health care system of the volunteering Members States.

DG SANTE also started to conceptualise a training programme on civil-military cooperation on health which will be based on a needs-analysis of the interested Member States.

Vaccination. DG SANTE continued its work to support regulatory actions, policy-related activities and access to COVID-19 vaccines, and support Member States in ensuring successful deployment and sufficient uptake of such vaccines. Following the respective recommendations from the European Medicines Agency (EMA), the Commission extended the authorisations for the COVID-19 vaccines to target new variants. The authorisation for Comirnaty was extended to target the JN.1 and the KP.2 virus variant on 3 July and 26 September, respectively; the authorisations for Spikevax and Nuvaxovid were extended to

target the JN.1 variant on 10 September and 8 October, respectively; the authorisation for Bimervax was extended to target the XBB.1.16 variant on 13 December. On 20 September, the Commission extended the authorisation of Imvanex, the only vaccine against Mpox currently authorised in the EU, for use in adolescents and issued an opinion regarding its use for children. On 28 June 2024, the Commission authorised the first-ever vaccine against Chikungunya virus – a disease transmitted by infected mosquitoes. While Chikungunya is not endemic in the EU, the effects of climate change have led to an increased presence of mosquitoes that transmit serious diseases in Europe. On 22 August, the Commission authorised mResvia, a vaccine indicated to prevent lower respiratory tract disease caused by Respiratory Syncytial Virus in adults 60 years of age and older.

DG SANTE's work on vaccination as a routine disease prevention and public health measure was in 2024 closely linked to the [Europe's Beating Cancer Plan](#). The [Recommendation](#) on vaccine-preventable cancers was adopted by the Council in June 2024. DG SANTE also finalised the implementation of the [Council Recommendation on strengthened cooperation against vaccine-preventable diseases](#) from 2018.



Under the United In Protection campaign, editable material and toolkits were developed to encourage vaccination against HPV, HBV and childhood diseases such as measles and pertussis. A paid social media campaign ran until September and a “Back to School” campaign was launched to remind parents and clinicians of the importance of full immunisation for young children. DG SANTE also actively participated in corporate initiatives to address mis- and disinformation, notably through the Network Against

Disinformation.

Antimicrobial Resistance (AMR).

DG SANTE worked with EU Agencies, stakeholders, and Member States through the AMR One Health Network on the implementation of the Council Recommendation adopted in 2023 to reach the national and EU 2030 targets on antimicrobial resistance and consumption. To assess progress in achieving the targets, a monitoring framework establishing indicators was finalized. A feasibility study to identify barriers and key enablers for integrated surveillance systems on antimicrobial resistance and consumption was launched.

In human health, DG SANTE continued monitoring the progress to the targets under the Council Recommendation, with the help of ECDC, published on the European Antibiotic Awareness Day. The data released in 2024 showed that accelerated efforts are needed in Member States to reach the targets in 2030.

The new joint action on AMR (EU JAMRAI 2) was launched in February 2024, with €50 million allocated under the EU4Health programme to support the implementation of the Council Recommendation, bringing together all EU Member States, Norway, Iceland, and Ukraine.

CurbingAMR is a key element of the EU Global Health Strategy and DG SANTE has taken forward work with international partners to advocate for its inclusion in the Pandemic Agreement. DG SANTE actively contributed to the United Nations General Assembly (UNGA) Political Declaration and participated at the High-Level Meeting on AMR in September 2024. Global commitments include the target of reducing the number of global deaths from bacterial AMR by 10% by 2030. DG SANTE participated to the follow-up Ministerial Conference hosted by the Kingdom of Saudi Arabia and continued to advocate for concrete global actions and commitments in international fora, including Codex, the G7 and the G20.

Coinciding with the UNGA, the EU-wide communication campaign “Beat the Bug” targeting young people included a game on the popular Fortnite gaming platform and influencer activity, reaching over 7 million people.



The EU continued the strong collaboration with global partners such as the United States, Canada, Norway, and the United Kingdom in the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR). It was also instrumental for informal exchanges in the run-up to the UN General Assembly High-Level meeting on AMR.

Other engagement at international level. The EU Global Health Strategy (GHS), adopted

in November 2022 and endorsed by the Council in January 2024, aims to regain lost ground towards achieving the health targets of the 2030 Sustainable Development Agenda and reinforce global capacities to prevent and combat health threats. DG SANTE continued to coordinate and contribute to the implementation of the Strategy along its 20 Guiding Principles. A study to set up a GHS implementation monitoring framework was launched and the first implementation report is due in 2025. A Joint Action on Global Health Impact has also been launched, with 2024 as the first full year of its operation.

DG SANTE continued to lead in pandemic agreement negotiations, and contributed to the design and implementation of an interim mechanism hosted by the WHO to enhance equity in medical countermeasures, helping close a key gap in tackling future pandemics

DG SANTE made a comprehensive contribution to advancing global health security. It proactively contributed in the G7 and G20 to galvanise their support for important global health work: digital health, the One Health approach, global action on AMR, climate change, equitable access to vaccines and health products by boosting local and regional manufacturing capacities and global cooperation on Long Covid. SANTE continued to champion the importance of universal health coverage and health system strengthening for the achievement of the health-related targets of the UN 2030 Sustainable Development Agenda including in the G7 and G20 contexts.

On 1 June 2024, an agreement was reached at the World Health Assembly in Geneva on a set of amendments to the International Health Regulations of 2005 (IHR). This is a significant step forward in how countries around the world work together to prevent, prepare for and respond to major health threats and improve the global health security architecture, two fundamental priorities of EU action in the field of global health. As the EU is not a party to the IHR, the Commission adopted in November 2024 a proposal for a Council Decision, asking EU Member States to accept the amendments.

DG SANTE contributed to the design and implementation of an interim mechanism hosted by the WHO to enhance equity in medical countermeasures, helping close a key gap in tackling future pandemics.

DG SANTE co-led the EU work in the Pandemic Fund, which over 2024 has become a key global tool to close important gaps in pandemic preparedness and prevention in lower income economies.

It also led the EU's drive to strengthen cooperation on global health security with high-income partners through its work in the Global Health Security Initiative and its participation in the so-called foreign affairs channel with the US and other partners—both of which allowed for the exchange of essential information and for the coordination of security actions across the full PPR spectrum.

DG SANTE equally drove the work to enhance cooperation on global health security with African partners, culminating on the agreement to enhance the EU-AU strategic health partnership in areas such as strengthening health systems and PPR; One Health approach and fighting Anti-Microbial Resistance; and fast-tracking the digital transformation of health.

Many of these strands came together as DG SANTE co-led the EU's comprehensive support to African partners and the WHO in responding to the mpox outbreak, which has been instrumental in the efforts to control the emergency.

In September 2024, DG SANTE launched an EU-Canada Health Policy Dialogue to advance common health priorities (antimicrobial resistance, health security, and non-communicable diseases) share knowledge, scientific evidence, and best practices to advance the health and safety of people in Europe, Canada and around the world.

Specific Objective 2.4: More effective, accessible and resilient health systems

Digital Health. In spring 2024, the European Parliament and the Council reached a political agreement on the [Commission proposal for a Regulation on the European Health Data Space \(EHDS\)](#). DG SANTE supported the co-legislators in the finalisation process; a corrigendum was approved in the December 2024 European Parliament Plenary and the Council then adopted the text in January 2025. The adopted Regulation is [expected to be published](#) in the Official Journal in early 2025.

In parallel, preparatory activities for the implementation of the European Health Data Space Regulation continued. On primary use of health data, DG SANTE continued to support and coordinate the actions of Member States in the eHealth Network on updating guidelines and exchanging best practices, and in the eHealth Member States Expert Group (eHMSEG) on deploying the MyHealth@EU infrastructure for cross-border exchanges of electronic Patient Summaries and ePrescriptions and its expansion to laboratory results, medical images and hospital discharge reports. Thanks to this work, three new Member States joined MyHealth@EU and the work on the development of laboratory results services was completed. Work continued on the Joint Action on primary uses to prepare the ground for the definition of the Electronic Health Record exchange Format (EEHRxF) and the specifications for electronic health record (EHR) systems. **On the secondary use of data**, DG SANTE has been advancing the establishment of a comprehensive governance framework for access to health data, ensuring interoperability and enhancing data quality and preparatory work for setting up HealthData@EU infrastructure for sharing of health data across Member States for secondary use purposes. The HealthData@EU pilot project has delivered initial versions of the central interoperability platform. Additionally, a new Joint Action on the secondary use of health data was launched in May 2024, focusing on the provision of practical guidance and the development of technical specifications to support the implementation of secondary use under the EHDS framework. In 2024, calls for new direct grants to Member States from the EU4Health programme were launched to support the rollout of MyHealth@EU and HealthData@EU. The work on the direct grants from work programmes 2021 to 2023 of EU4Health continued, including on the European vaccination card. Thanks to these direct grants, the establishment of health data access bodies for secondary use and implementation for over 80% of the MyHealth@EU services by Member States that will become mandatory in 2029 have already started.

DG SANTE continued strengthening its commitment towards the international dimension of digital health by ensuring cooperation with international organisations, for example through WHO projects supported from EU4Health to strengthen health information systems and boost health data governance and interoperability across the European Region, and on the deployment and scaling of the Global Digital Health Certification Network (GDHCN), and participation in the OECD initiative on challenges to scale up AI in healthcare. DG SANTE also established bilateral collaboration with the United States through regular exchanges and knowledge sharing with the relevant authorities and agencies through the “US/EU Digital Health Work Stream”.

Health systems. DG SANTE has continued to work in collaboration with SG-RECOVER, ECFIN and EMPL to assess health-related investments and reforms proposed in the Recovery and Resilience Plans and monitor their implementation. All of the 27 national plans adopted include measures related to health which add up to a total of EUR 43 billion. In addition, DG SANTE contributed to the 2024 European Semester, by focusing on the relevant health challenges and recommendations and drafting the thematic Annex on Health and Health Systems in all 27 countries⁹. In November 2024 of the [Health at a Glance report](#) prepared by OECD in cooperation with the Commission was published. The report, which is published every two years, presents an assessment of the EU’s progress toward effective, accessible, and resilient health systems based on publicly available data and indicators. The 2024 edition focusses in particular on the two interconnected priorities of promoting healthy longevity and addressing health workforce shortages.

In 2024, DG SANTE continued to act as secretariat for the Expert Group on Health Systems Performance Assessment, which has a broadened mandate to focus on a more strategic approach to transforming health systems. The Expert Group worked on a report identifying low-value healthcare and measures or strategies to reduce low-value care, to be published in February 2025 with a webinar. The next priority topic for the expert group is health workforce, focusing on Member States’ approaches to safe staffing levels. The implementation of a portfolio of projects under EU4Health addressing health systems and access to healthcare continued, for example: the Joint Action CIRCE-JA on the transfer of best practices in primary care, and a project carried out by the WHO on supporting Member States to improve financial protection and affordability of healthcare, the project led by the JRC to develop metrics to assess the impact of healthcare on reduction of poverty and inequalities and the action, which will provide guidelines to improve access to healthcare for persons with disabilities.

Following the [evaluation](#) of the first five years of operation of the 24 [European Reference Networks](#) (ERNs), DG SANTE continued to support the development and the improvement of the functioning of the networks. In February 2024 a three-year Joint Action with a budget of

⁹ The Health Annexes are part of the Country Reports which are published on this page: [2024 European Semester: Country Reports - European Commission](#)

€18.75 million was launched in order to better integrate ERNs in national health systems and develop patient pathways. It involves all EU Member States, Norway and Ukraine.

Substances of human origin (SoHO). The [new Regulation on standards of quality and safety Substances of Human Origin \(SoHO\)](#) was adopted by the co-legislators in July 2024. To prepare for the entry into application of the new framework in 2027, DG SANTE started the development of a dedicated IT platform, established collaborations with the newly appointed expert bodies (ECDC and EDQM), prepared for the set-up of a SoHO Coordination Board, and for the development of oversight tasks, in close collaboration with the SoHO authorities.

Health Workforce. The Commission put in place several actions to support Member States in addressing staff shortages and skills mismatches. In addition to the EU4health funding [Joint action HEROES on health workforce planning and forecasting](#), training projects with emphasis on digital skills, a new project was launched with WHO Europe addressing nurse shortages in Europe. and SANTE continues to steer the Pact for Skills large-scale partnership of the health workforce under Erasmus+ programme. Five projects funded under the Third Health programme, focused on shortages of medical staff in medical deserts, retention policies and task-shifting, came to an end by mid- 2024.

Patients' right to cross-border healthcare. The main objective of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare is to facilitate access to safe and high-quality healthcare in another Member State. The Directive also provides the legal basis for the European Reference Networks for low prevalence, rare and complex diseases, the recognition of prescriptions and cooperation on cross-border healthcare in border regions. The last evaluation of the Directive, in May 2022, showed that EU citizens are still not well informed about their cross-border healthcare rights. Awareness of ERNs is also low.

As a follow-up action of the 2022 evaluation of the directive, a series of workshops with policy makers, citizens, healthcare providers and insurers were organised in Malta, Italy, Ireland, Poland, Finland and in border regions which include workshop jointly organised by Greece/Cyprus, Estonia/Latvia and Belgium/Netherlands. The workshops aimed to raise awareness about patients' rights in cross- border healthcare including the European Reference Networks, and their activities for patients affected by a rare disease. In addition, a new [Omnibus Directive](#) amending Directive 2011/24/EU was adopted bringing the evaluation of the implementation of the directive in line with the evaluation of the European Reference Networks.

All the European Reference Networks' (for rare and complex diseases) grants have been signed, thus supporting the coordination of the 24 ERNs until 2027. A Joint Action has been launched supporting Member States to better integrate the European Reference Networks into national health systems. In addition, DG SANTE has launched a new IT platform for cross-border medical discussions on rare diseases – the Clinical Patient Management System 2.0 (CPMS 2.0) – in order to support the European Reference Networks.

2. INTERNAL CONTROL AND FINANCIAL MANAGEMENT

Management monitors the functioning of the internal control systems on a continuous basis and carries out an objective assessment of their efficiency and effectiveness. In annex 7, there is a list and details of the reports that have been considered. The results of the above assessment are explicitly documented and reported to the Director-General.

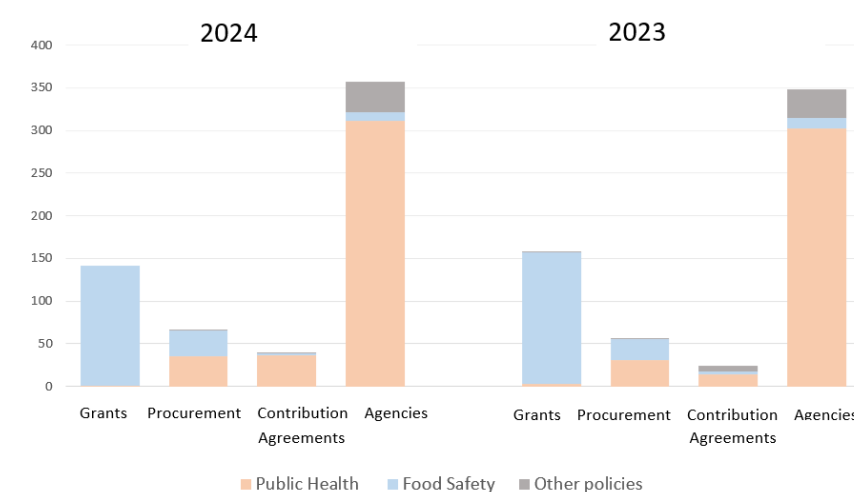
2.1. Control results

Management uses control results to support its assurance and reaches a conclusion about the cost-effectiveness of those controls, meaning whether the right balance between the following elements is achieved (i) **Effectiveness**: the level of error found, based on the controls carried out; (ii) **Efficiency**: the average time taken to inform or pay; (iii) **Economy**: the proportionality between the costs of controls and the funds managed.

2.1.1. Overview of the budget and relevant control systems (RCS)

This section covers all expenditure and other significant non-expenditure items ⁽¹⁰⁾. DG SANTE managed financial operations under its two policy areas, Health and Food Safety, and under funds delegated from other policy areas. 2024 was the fourth year of implementing the new Multi-annual Financial Framework (MFF) covering the 7-year period from 2021 to 2027 ⁽¹¹⁾.

Figure 2.1 DG SANTE's 2024 budget implementation in comparison to 2023
(Payments made in 2024: EUR 606 million (2023: EUR 589 million))



⁽¹⁰⁾ These include only the significant amounts, i.e. assets (intangible assets exceeding EUR 5 million and "Inventories" exceeding EUR 1 million); no other items were significant in 2024.

⁽¹¹⁾ Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020.

About 44% of the 2024 budget implemented by DG SANTE fell under direct management, mainly through grant agreements and public procurement; DG SANTE implemented the remaining 56% under indirect management of which 11,5% for contribution agreements, mainly with international organisations (see Annex 11), and 88,5% for subsidy payments to four EU decentralised agencies for implementing their tasks (see Annex 13).

The assurance building processes rely, first and foremost, on errors found in on-the-spot financial controls and audit conclusions of the European Court of Auditors and the Commission's Internal Audit Service. Risk management helps establish and maintain specific internal control strategies focussing on the activities and domains representing the highest risks. DG SANTE's assurance building, and materiality criteria are outlined in Annex 5 while Annex 6 outlines the main risks together with the control processes to mitigate them and the indicators used to measure the performance of the relevant control systems (RCS). The control results are described in Annex 7.

EU4Health Programme – 2024 work programme

- Under the general objective 2 “Promoting our European way of life”, The EU4Health Programme¹² aims to complement, support and add value to the policies of Member States in (i) improving the health of EU citizens by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare; (ii) protecting the EU from serious cross-border threats to health; (iii) improving the availability, accessibility and affordability of medicinal products, medical devices, crisis-relevant products and supporting innovation regarding such products; and (iv) strengthening health systems by improving their resilience and resource efficiency.
- The EU4Health Programme had initially an envelope of EUR 5.3 billion (2021-2027) that has been reduced by EUR 1 billion following the decision of the European Council. This cut represents a 20%-reduction of the total programme budget and affects the EU4Health budgets for 2025 to 2027.
- DG SANTE's spending in the Health policy area remained relatively stable over the last three years. In 2024, DG SANTE managed a budget of EUR 327.5 million in payment credits, mainly for the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe and the implementation of Union health legislation in general. HaDEA implemented about 78% of the payment budget while DG SANTE implemented the remaining 22% (EUR 71.5 million) mainly through contribution agreements with international organisations and public procurement procedures.

Food Safety expenditure

- DG SANTE's work on safe and sustainable food contributes to the general objective 1 “European Green Deal”. By far the largest share of the budget of the Single Market

¹² Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme; C(2022) 317 of 14 January 2022 – 2022 work programme of EU4Health

Programme (SMP)-Food chain strand¹³ (EUR 1.7 billion for the period 2021-2027) is allocated to “Food and feed safety” to cover disease prevention. Smaller parts of the budget support “Sustainable food systems – the ‘Farm to Fork’ Strategy” and “International promotion of EU food safety standards”.

- DG SANTE’s payment credits of the SMP-Food chain strand in 2024 amounted to EUR 252.3 million of which about 32% were implemented by HaDEA to co-finance Member States’ veterinary and phytosanitary programmes, the European Reference Laboratories and Centres, and the Member States’ control plans for antimicrobial resistance (AMR) monitoring. DG SANTE implemented 68% (EUR 172.5 million) of which EUR 140 million for veterinary and phytosanitary emergency measures in the form of grants to Member States based on co-financing of eligible costs. The share of contributions to the emergency measures remains high due to the many outbreaks of Avian Influenza and African Swine Fever in the past few years.

Other policy areas

- An amount of EUR 36.2 million was co-delegated to DG SANTE from DGs RTD and CNECT to pay their respective share of the subsidy to HaDEA’s running costs for 2024.
- DG SANTE paid EUR 1.6 million from budget delegated by DG HOME a contribution agreement with the International Federation of the Red Cross and Red Crescent Societies to support mental health and psychosocial assistance for displaced people coming from Ukraine.

Agencies

- DG SANTE paid subsidies to finance – partially or in full – the operating budget of HaDEA (EUR 19.3 million) and four EU decentralised agencies (EUR 301.6 million).

Building expenditure for Grange, Ireland

- About EUR 2 million relate to the office building in Grange, which is managed directly by DG SANTE (not by OIB or OIL).

Balance sheet:

- In its balance sheet, DG SANTE identified internally generated intangible assets of a total value of EUR 31 million at 31 December 2024. The assets pertain to IT software developed by DG SANTE for eHealth (EUR 19.7 million) and EUDAMED (EUR 11.4 million; European database for medical devices).

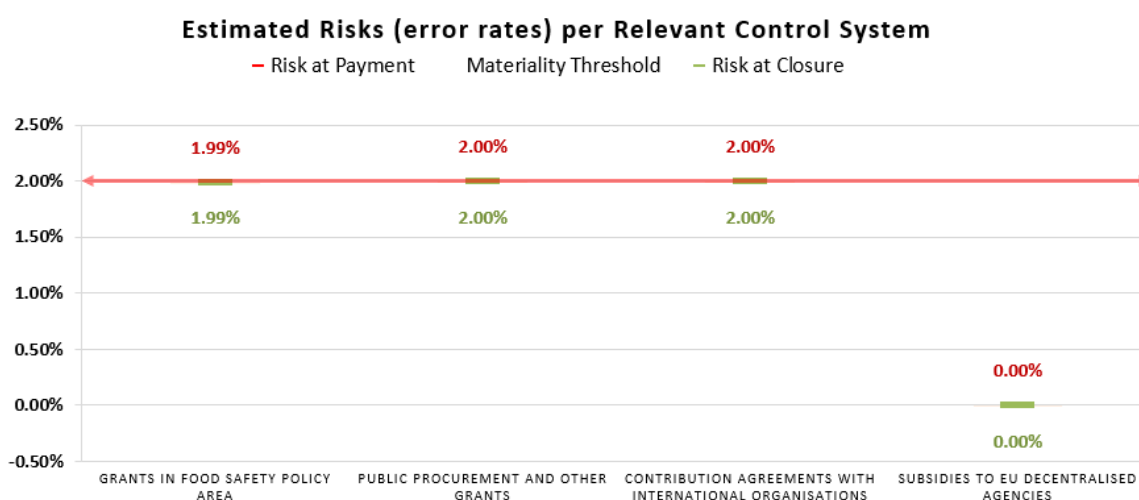
¹³ Regulation (EU) 2021/690 of 28 April 2021 – SMP; C(2021)3046 of 6 May 2021 – work programme 2021-2022 for the food chain strand of the SMP

- In addition, DG SANTE identified current assets (inventories) of a total value of EUR 12.5 million at 31 December 2024. The assets pertain to antigen stocks for Foot and Mouth Disease in order to carry out emergency vaccination.

2.1.2. Effectiveness of controls

(a) Assessment of control results per relevant control system for expenditure

Figure 2.1 Estimated risks per relevant control system of budget activity



DG SANTE's budget implementation

The most relevant key indicators to assess the control results are the **“risk at payment”** and **“risk at closure”** for the different types of expenditure that DG SANTE managed in 2024. DG SANTE assessed the risk at closure based on equivalent estimates to the detected error rates as it does not carry out ex-post controls anymore, since the transfer of budget implementation tasks, including ex-post controls, to HaDEA in 2021.

The grants that remain with DG SANTE are grants to Member States for their animal and plant health emergency measures. DG SANTE estimates an equivalent to the detected error of 2.0% for these grants based on own past experience and HaDEA's results of ex-post controls on Member States' animal and plant health programmes. Moreover, DG SANTE carries out in-depth ex-ante controls of each cost claim before the final payment is made, including a sample of financial audits in the Member States.

Payments related to public procurement are based mostly on fix-price contracts for which the error rate is estimated cautiously at just under 2%.

DG SANTE has not yet carried out ex-post controls on payments made for contribution agreements to international organisations under indirect management and estimates an

equivalent to the detected error of just under 2% which is a cautious approach given the error rates found by DG INTPA.

The error rate for the subsidy payments to agencies is set at 0% as these payments cover the agencies' establishment and core tasks which are considered error-free types of expenditure; in addition, all subsidy payments are based on the agencies' final accounts audited by the Court of Auditors.

The future corrections are prudently estimated at 0%. This results in an estimated overall risk at closure of **0.51% for 2024**. In the last seven years, the overall risk at closure has not exceeded the materiality threshold of 2% (materiality is assessed in accordance with Annex 5). The coverage of the Internal Control Objectives and their related main indicators are described in more detail in Annexes 6.

The analysis of all available control results (see Annex 7.1), the assessment of the weaknesses identified and that of their relative impact on legality and regularity, has not revealed any significant issues which could have a material impact as regards the legality and regularity of the financial operations. Thus, DG SANTE concludes that the control objectives as regards legality and regularity have been achieved.

Supervision of the executive agency and the decentralised agencies

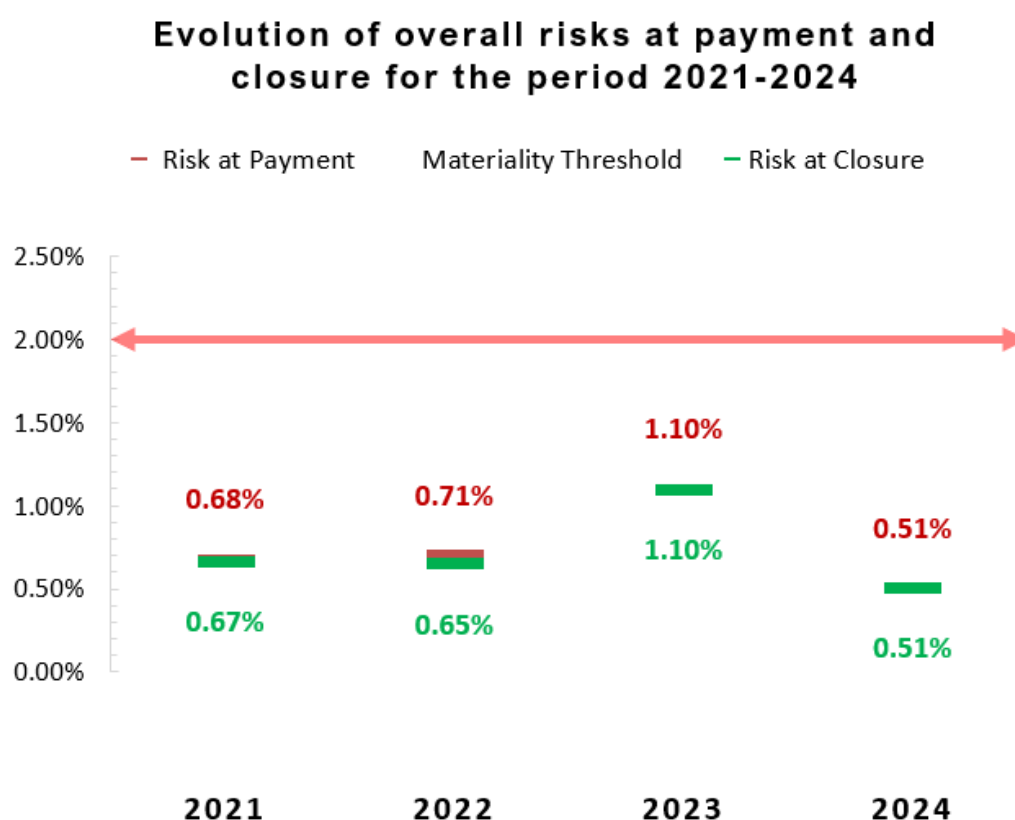
The executive agency HaDEA has signalled no serious control issues and no reservation was made in the implementation of the EU4Health Programme or Single Market Programme. See the Annual Activity Report 2024 of HaDEA. DG SANTE's mechanism for supervision/coordination, monitoring and reporting encompasses the work of the Steering Committee, participation in SANTE/HaDEA Management Board meetings, regular meetings at senior management level and day-to-day interactions at Unit level (see Annex 7.1.1.4 for more detail).

With regard to the four EU decentralised agencies (EFSA, EMA, CPVO, and ECHA's biocides activities) for which DG SANTE was responsible in 2024, the European Court of Auditors (ECA) gave a positive declaration of assurance for the year 2023. The "emphasis of matter" in ECA's 2023 audit report on EMA relating to the former office building in London and other comments made by the Court do not call into question DG SANTE's reasonable assurance on the operating budget managed by the EU agencies. From its own monitoring and supervision work as a responsible DG, DG SANTE did not become aware of anything that would indicate that the reporting from the agencies would not be reliable.

In view of DG SANTE's residual responsibility for the management of the parts of the budget transferred to HaDEA, as well as for the funds paid to the operating budgets of the agencies, DG SANTE concludes that there are no control weaknesses affecting the assurance building in terms of the control objective as regards legality and regularity. Given that the subsidy is directly voted by the Budgetary Authority (for tasks directly entrusted by the legislator), the management of each agency bears ultimate responsibility for the legality and regularity of the transactions.

(b) Estimation of the overall risk at payment and risk at closure

Figure 2.3 Evolution of overall risks at payment and closure during 2021-2024



The estimated overall risk at payment for 2024 expenditure is the AOD's best conservative estimate of the amount of relevant expenditure during the year, not in conformity with the contractual and regulatory provisions applicable at the time the payment was made. As DG SANTE carries out only ex-ante controls, this expenditure will not be subject to subsequent ex-post controls. Consequently, for the risk at payment and risk at closure, DG SANTE is using a flat rate of 2.0% as a conservative estimate for expenditure based on grants, procurement and contribution agreements with international organisations and the Commission's flat rate of 0.0% for subsidy payments to agencies. There is a relatively stable trend since 2018 mainly due to the continuously high share (almost 80%) of low-risk types of expenditure with a risk at payment of 0.5% or 0.0% (see Annex 9).

For an overview at Commission level, the departments' estimated overall risk at payment, estimated future corrections and risk at closure are consolidated in the AMPR.

(c) Qualitative benefits of controls: Preventive and corrective measures

With its ex-ante controls before the final payment, DG SANTE has an effective mechanism in place for detecting and correcting errors, reaching in total EUR 4.3 million of corrections

for 2024. In this amount is also included EUR 0.6 million that has been recovered following and ex-post audit (EUR 3.7 million for ex-ante controls and EUR 0.6 million for ex-post controls, compared to last year to EUR 1.6 million and EUR 0.2 million respectively). For more details see annex 3 table 8.

(d) Assessment of control results for non-expenditure items

In its balance sheet, DG SANTE identified internally generated intangible assets of a total value of EUR 31 million at 31 December 2024. The assets pertain to IT software developed by DG SANTE for eHealth (EUR 19.7 million) and EUDAMED (EUR 11.4 million; European database for medical devices). DG SANTE uses Framework Contracts of DG DIGIT to procure IT services for IT development which account for the largest part of the value of the assets. As the valuation is automatised through ABAC Assets modules, the risk of error is very limited. In addition, DG SANTE identified current assets (inventories) of a total value of EUR 12.5 million at 31 December 2024. The assets pertain to antigen stocks for Foot and Mouth Disease in order to carry out emergency vaccination.

The main aim of accounting controls is to assure the quality and reliability of the accounts and underlying transactions through methodical checks on the accounting records (data) and timely communication and correction of the errors.

In conclusion, DG SANTE considers the current control arrangements for accounting and financial reporting to be sufficient. They work in practice as intended. Proper safeguarding of the DG SANTE inventories was ensured throughout the year as stated in the reports received from the contractors.

(e) Fraud prevention, detection and correction

DG SANTE has developed and implemented its own anti-fraud strategy since 2013, based on the methodology provided by OLAF. It is updated every three years and was last updated on 8 November 2021 following a fraud risk assessment. Its implementation is being monitored and reported to the management twice a year. All necessary actions, except for some awareness raising actions and the update of the anti-fraud strategy (2021-2024), have been implemented resulting in an implementation rate of more than 80%. The anti-fraud strategy is expected to be updated to cover the years (2025-2027) in the first half of 2025 (detail is provided in Annex 71.2).

DG SANTE received no OLAF financial recommendations during the period 2020-2024. All follow-up actions to implement OLAF recommendations were closed before 2020.

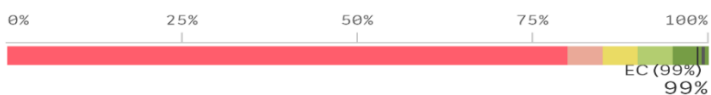
Other results achieved during the year thanks to the anti-fraud measures in place can be summarised as follows: in October 2024, DG SANTE in cooperation with DG HR and IDOC organised an info-session on Ethics and Professional Integrity, especially addressed to DG SANTE staff. Around 250 staff members of DG SANTE participated. As in previous years, DG SANTE representatives attended the Fraud Prevention and Detection Net events chaired by OLAF.

On the basis of the available information, DG SANTE has reasonable assurance that the anti-fraud measures in place are overall effective.

2.1.3. Efficiency of controls

The main efficiency indicators monitored in 2024 focussed on the timeliness of budget implementation. Thanks to timely budget transfers, DG SANTE achieved a 100% implementation of the 2024 must-use commitment credits and 100% of its expiring payment credits.

DG SANTE achieved **99% of timely payments** (in amounts). There were 67 late payments, mainly due to lack of staff dealing with the large volume of invoices, coming in waves. Supported by electronic workflows with automatic reminders of payments due, DG SANTE was able to keep up an efficient payment file handling in 2024. Efficiency indicators such as “time-to-inform” and “time-to-grant” were not applicable to DG SANTE’s grant agreements (for more indicators and explanations see Annexes 4 and 7.2).

Timely Payments	SANTE Score	EC Score
	99%	99%

2.1.4 Economy of controls

The main economy indicators monitored in 2024 focussed on the resources employed for internal control activities. They encompass DG SANTE’s staff carrying out the monitoring tasks through the different stages of the control processes as defined in Annex 6. The costs are based on estimates made – inter alia – in the Unit Management Plans approved by the Director-General. The average cost of control amounts to **1.4% of the total payments** of EUR 606.1 million made by DG SANTE in 2024 (for more detail see Annex 7).¹⁴

The management of grants co-financing Member States’ veterinary and plant emergency measures is demanding, the main cost-drivers being the diversity and complexity of the files in both technical and financial aspects.

Public procurement procedures are highly regulated and compliance and good quality must be ensured in each process. DG SANTE purchases typically services in new fields and technically complex environments entailing a relatively high workload for drafting tender specifications. As the control costs for safeguarding of assets are marginal and not attributable to a separate control system, they are grouped under procurement.

DG SANTE concludes contribution agreements only with pillar assessed international organisations. The cost of control reflects the diversity of agreements with technical preparations and monitoring of the work performed.

¹⁴ The cost of controls for intangible assets and inventories is included in the DG’s total amount and cannot be provided separately.

Subsidy payments to agencies are cost driven by the annual exercises of drafting the Commission opinions on the agencies' Strategic Programming Documents (SPDs), DG SANTE's preparation for and attendance of Management Boards and, where applicable, Audit Committees, the follow-up of the regular external evaluations of the agencies and numerous bilateral contacts at all hierarchical levels.

2.1.5 Conclusion on the cost-effectiveness of controls

Based on the most relevant key indicators and control results reported above, DG SANTE has assessed the effectiveness, efficiency and economy of its control system and reached a **positive conclusion on the cost-effectiveness of the controls for which it is responsible.**

DG SANTE's control environment and control strategy for grants, public procurement, contribution agreements to international organisations and subsidy payments to agencies remained stable during the reporting year compared to previous years. DG SANTE considers that its control strategy is cost-effective overall, given the main cost drivers, and the efforts already taken over several years to reduce the cost of controls, without compromising the effectiveness of controls and the timely payments.



2.2 Audit observations and recommendations





This section sets out briefly the state of play for all audit observations and recommendations reported by auditors related to internal control and financial management, including the limited conclusion of the Internal Auditor on the state of internal control. Further details can be found in Annex 8.

Where an audit has detected weaknesses affecting any internal control principal or the department's assurance, a detailed analysis is provided further below in section 2.3 and 2.4, accordingly.

2.2.1 Internal Audit Service of the Commission















In its contribution to the 2024 Annual Activity Report process, the Internal Audit Service concluded that based on the audit work performed in the period 2020 to 2024, the IAS points to one open recommendation rated 'very important', and as a result concludes that "the internal control systems in place for the audited processes are effective, except for the observations giving rise to the 'very important' recommendation". The open recommendation pertains to the internal audit on the Commission actions against food fraud in DGs SANTE and AGRI and OLAF for which the audit report was finalised on 30 January 2023. DG SANTE's implementation of the action plan is well on track with a target date in mid-2025 (see Annex 8.1.1).

Reported	Audit Title	Accepted Recommendation	State of play in 2024	Impact on the assurance for 2024
2023	IAS audit on European Commission actions against food fraud in DG SANTE, DG AGRI and OLAF	Very important: No. 6 (actions ongoing with target dates in mid-2025)		

-  Action plan implemented and closed by IAS or ECA / No impact on the assurance
-  Action plan implementation is ongoing or awaiting review from IAS or ECA
-  Preparation of the action plan
-  Impact on the assurance

DG SANTE believes that thanks to the mitigating measures already put in place in 2023 and 2024, the open audit recommendation does not call into question the effectiveness of DG SANTE's internal control system and that the identified weaknesses do not warrant a reservation to the annual declaration of the Director-General of DG SANTE. Please see Annex 8.1 for more detail.

2.2.2 European Court of Auditors

Reported	Audit Title	Accepted Recommendation	State of play in 2024	Impact on the assurance for 2024
2024	Declaration of Assurance (DAS) on the 2023 accounts and transactions (ECA annual report)	None		
2024	The EU's response to the COVID-19 pandemic (Special Report No 12/2024)	1 recommendation addressed to SANTE: preparation of action plan ongoing		
2024	Digitalisation of Health Care (Special Report No 25/2024)	1 recommendation addressed to SANTE: preparation of action plan ongoing		
2024	Food labelling in the EU (Special Report No 23/2024)	5 recommendations addressed to SANTE: preparation of action plan ongoing		
2023	Tools facilitating travel within the EU during the COVID-19 pandemic (Special Report No 01/2023)	2 recommendations addressed to SANTE of which 1 is fully implemented and 1 partially implemented		
2020	Protection of wild pollinators in the EU (Special Report No 15/2020)	2 recommendations addressed to SANTE of which 1 was fully implemented and 1 partially implemented		
2018	Animal welfare in the EU (Special Report No 31/2018)	5 recommendations addressed to SANTE of which 3 were fully implemented and 2 partially implemented		

Reported	Audit Title	Accepted Recommendation	State of play in 2024	Impact on the assurance for 2024
2016	Combating Food Waste (Special Report No 34/2016)	3 recommendations addressed to SANTE. 1 remaining partially implemented recommendation was fully implemented in 2024.	✓	✓

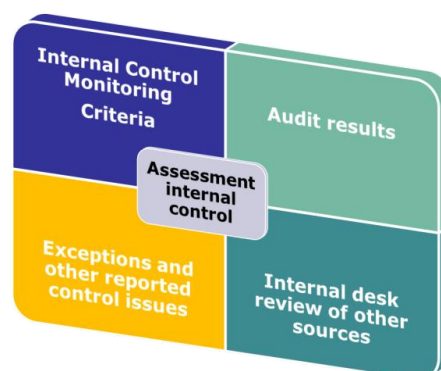
DG SANTE's implementation of audit recommendations is based on action plans regularly monitored and audited. The full implementation of the two recommendations on “Animal Welfare” is delayed as key steps in DG SANTE’s developing Commission proposals were outside DG SANTE’s control. Detail on the Court’s recommendations and DG SANTE’s follow-up actions are included in Annex 8.1.2.

None of the issues raised by the auditors met the materiality criteria set out in Annex 5: no critical recommendation was made; no significant repetitive error or material deficiency in the internal control systems of DG SANTE was highlighted. The issues addressed by the Court of Auditors or the weaknesses found by the IAS do not point to significant quantifiable errors or elements that could damage the reputation of the Commission. Therefore, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General of DG SANTE.

2.3 Assessment of the effectiveness of internal control systems

The Commission has adopted an Internal Control Framework based on the highest international standards⁽¹⁵⁾.

DG SANTE has adapted the Internal Control Framework to its specific characteristics and organisational structure. The internal control systems are suited to achieving its policy and internal control objectives in accordance with the internal control principles, having due regard to the risks associated with the environment in which it operates.



DG SANTE has assessed its internal control system during the reporting year¹⁶ and has concluded that it is effective, and the components and principles are present and functioning well overall, but some improvements are needed as minor deficiencies were identified related to controls over technology, ethics, staff allocation and professional development,

⁽¹⁵⁾ The Committee of Sponsoring Organizations of the Treadway Commission Internal Control Integrated Framework, the golden standard for internal control systems.

⁽¹⁶⁾ The main sources of information and details of the assessment are described in Annex 8.2.

functions that are only partially under DG SANTE management. To address these issues, awareness raising efforts related to “ethics” as identified in the action plan of the anti-fraud strategy as well as ‘Be Well at Work’ initiatives will be reinforced in 2025.

2.4 Conclusions on the assurance

The information reported in section 2.1 stems from the results of management and feedback received in audit reports listed above. This approach provides sufficient guarantees as to the completeness and reliability of the information reported and results in a full coverage of the budget delegated to the Director-General of DG SANTE.

In the last seven years, the overall risk at closure has not exceeded the materiality threshold of 2% (materiality is assessed in accordance with Annex 5). In 2024, it amounts to 0,51%. For the budget implementation tasks transferred to HaDEA, DG SANTE has adequate supervisory measures in place. In view of DG SANTE’s residual responsibility of the funds paid to the operating budgets of the EU decentralised agencies, and the positive declarations of assurance of the European Court of Auditors (ECA) for the agencies’ accounts and financial transactions of the year 2023, DG SANTE concludes that there are no control weaknesses affecting the assurance building.

As reported in section 2.2, none of the issues raised by internal and external auditors met the qualitative materiality criteria: no critical recommendation was made; no significant repetitive error or material deficiency in the internal control systems of DG SANTE was highlighted; neither were elements identified that could seriously damage the reputation of DG SANTE.

Based on DG SANTE’s own assessment of its internal control system in section 2.3, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General.

In conclusion, based on the elements reported above, management has reasonable assurance that, overall, **suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented.** The Director-General, in her capacity as Authorising Officer by Delegation has signed the Declaration of Assurance.

Declaration of Assurance

Declaration of Assurance

I, the undersigned,

Director-General of DG SANTE

In my capacity as authorising officer by delegation

Declare that the information contained in this report gives a true and fair view ⁽¹⁷⁾.

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex-post controls, the work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.

Confirm that I am not aware of anything not reported here which could harm the interests of the institution.

Brussels, date 31 March 2025

(e-signed)

Sandra GALLINA

⁽¹⁷⁾ True and fair in this context means a reliable, complete and correct view on the state of affairs in the DG/Executive Agency.

3. MODERNISING THE ADMINISTRATION

3.1 Human resource management

In 2024, DG SANTE invested intensively in filling the vacancies as rapid as possible and in ensuring maximal use of the available credits for recruiting staff. The reserve lists – still available for recruiting specialists in DG SANTE’s activity domains – were exploited to the maximum, supplemented by the temporary agents where needed. By the end of the year, the vacancy rate of statutory posts decreased to less than 2,5%. More indicators are provided in Annex 10.

DG SANTE has made important progress to achieve gender balance in management functions. With the recruitment of an additional female Deputy Director-General, Director and two Heads of Unit, DG SANTE has now more female than male managers.

The Director-General continued in collaboration with the Senior Management Team to promote staff engagement by stimulating collaboration and communication through clear communication channels from top to bottom and vice versa, promoting staff involvement and the provision of valuable feedback. DG SANTE celebrated its 25th anniversary on its three geographical sites. It helped to strengthen the bonds between newcomers and more senior staff by exchanging experiences and building a bridge from SANTE’s past into SANTE’s future. Further to many recent changes of the Senior management team, five Directorates each organised their one-day staff seminar; many information sessions and thematical discussions were organised to ensure that staff is onboard and aligned with the policy and administrative files and processes at stake. Most importantly, we emphasised data security and Artificial Intelligence.

Considerable attention was also paid to organise workshops and plenary sessions preparing and planning for the new Commission mandate starting on 1 December 2024. At the same time, DG SANTE pushed many files to the final decision-making stages by the end of President Ursula von der Leyen’s first mandate, and thus, put the organisation and the staff under high stress. Therefore, the work intended on initiatives aiming at promoting DG SANTE’s culture of caring and ‘Be Well at Work’ had to be postponed to 2025.

3.2 Digital transformation and information management

DG SANTE has been investing in its digital transformation as a strategic instrument and in 2024, has proposed an IT modernisation and rationalisation approach, following a review of its portfolio (for a detailed description see Annex 10).

Using the high-level cartography of our business and related technical solutions, we established a classification of solutions and a rationalisation and modernisation plan to strengthen the use of large critical and corporate systems and solutions and absorb or phase out other systems. DG SANTE implements its digital transformation across the axes defined by the corporate bodies and new digital strategy, pursuing a practical stepwise approach

with the aim to streamline and modernise the portfolio of solutions in business terms by simplifying processes and digital implementation, technical terms and by moving to the cloud and more connected systems. We have continued to adjust the approach to delivering and procuring IT solutions and services to be more reactive, agile and business oriented, and in line with the corporate 'dual-pillar' approach. DG SANTE joined the corporate initiative for the European Crisis Management Platform (ECMP), confirming the full participation of the future EWRS solution on this platform. The digital transformation and information management in DG SANTE are defined in DG SANTE's Digital and Data Master Plan (DDMP) for 2024. The 2024 DDMP implementation report, due in Q1 2025, will detail all actions and implementation details for the previous year.

With regard to Data Protection, in 2024, DG SANTE remained committed to the five key objectives of the Commission's Data Protection Action Plan (more detail is provided in Annex 10). As part of its annual operations, DG SANTE thoroughly reviewed and updated the existing records of its processing operations. To ensure the robust implementation of data protection by design and by default within DG SANTE's IT systems, both for new and existing ones, a collaborative effort was established between the DG SANTE Data Protection Coordinator and the IT Unit.

Please refer to Annex 10 of the AAR for details on the Digital Transformation in DG SANTE's work and alignment with the Commission Digital Strategy's five strategic objectives.

3.3 Sound environmental management

In 2024, DG SANTE maintained the European Commission's Environmental Management registration for its building in Grange and continued taking steps to reduce the use of natural resources and to limit the associated negative environmental impacts.

As in 2023, a section of the main office building in Grange remained shut throughout the year to continue reducing energy use. In addition, following the phasing-out of the on-site childcare service, the crèche building was withdrawn from active use. The lights in the main car park were replaced with LED lights and the work on gradual upgrading of the emergency lights throughout the building with LED lights continued.

In 2024, the use of VC meeting rooms increased slightly as compared with the year before, maintaining an encouraging year-on-year growth trend. Three important new contracts have been signed with external providers for the provision of site-critical services. Two of these contracts included green public procurement elements.

The Grange building is now over 20-years-old. Its age combined with the reduced footfall resulting from the hybrid working arrangements pose considerable maintenance challenges. In 2024, these factors had a particularly adverse effect on water-use efficiency. Going forward, the increased focus on maintenance, health & safety, and business continuity is likely to lock-in additional resources and, as a result, constrain the site's ability to continue making meaningful improvements of its environmental performance.

3.4 Examples of economy and efficiency

In its 2024 Management Plan, DG SANTE identified two initiatives to improve the efficiency and economy of its operations. The following progress was made in 2024:

1) Preparation for the use of the new corporate accounting tool SUMMA

In 2024, DG SANTE has spent considerable time in preparatory work, training and testing to ensure a smooth migration to SUMMA and has reached a readiness indicator of 100%. Once fully operational, SUMMA will modernise, harmonise and standardise EU financial business processes offering a significant increase in efficiency, flexibility and speed.

2) Cataloguing data

As of 2023, the Data and Digital Master Plan (DDMP) provides a common vehicle for DG SANTE to address Data and Digital needs in an integrated way and with a closer collaboration of the relevant SANTE teams. Work has focused on technologies and capabilities for data cataloguing and use of Artificial Intelligence as a tool to process large amounts of data. DG SANTE activities have progressed as follows: