



Annual Activity Report 2023

DG Health and Food Safety(SANTE)

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FOREWORD As we reflect on another year gone by, health and food safety are policy areas that continue to grow in pertinence and importance. With global trends such as climate change, the advancements in AI and an ageing population, our work at DG SANTE will only grow in salience.

The importance of our One Health approach in addressing the complex challenges we face today was reaffirmed in 2023. Whether in tackling antimicrobial resistance, responding to avian influenza outbreaks or considering the risk of climate change for human health, it is now clear that One Health is the only way forward. The successful One Health event that SANTE hosted in November provided ample evidence of the need to consolidate and intensify our work in this direction.

The European Health Union was born under this Commission and our proposals to reform the pharmaceutical legislation in April shall be seen as its ultimate pillar. We are pushing for a framework that is more agile, flexible and better adapted to the needs of citizens and businesses across the EU, with the aim of making medicines more available, accessible and affordable. The year also ended on a high for our Health Union, with a political agreement on the proposal for substances of human origin, which will substantially improve patient safety. Europe's Beating Cancer Plan also advanced this past year, with the publication of the first Country Cancer Profiles under the European Cancer Inequalities Registry and the launch of [dozens of projects](#) financed under the EU4Health Programme that will make a real difference on prevention, early detection, treatment and quality of life.

Although 2023 spelled the [official end](#) to COVID-19 as a Public Health Emergency of International Concern (PHEIC), we continued the crucial work to ensure that Europe is better prepared for future pandemics and to promote more resilient health systems. DG SANTE also worked closely with our international partners to ensure coordinated global action in this area. It was with great pride that, in July, we handed over the framework for the [EU Digital COVID Certificate](#) to the World Health Organisation, for global use. In a spirit of solidarity and ambition, we engaged in the international negotiations for a Pandemic Agreement. As the brutal war in Ukraine continued throughout 2023, DG SANTE continued to support of Ukrainian citizens in the area of public health, with actions and funding to address both their physical and mental health needs. These actions exemplify DG SANTE's wide contribution to the implementation of [EU Global Health Strategy](#), which are referenced throughout this report.

In 2023, we also shone a light on mental health in the EU like never before, as reflected by the [Comprehensive approach](#) adopted in June. This light must never be allowed to go out. Our Comprehensive Approach introduced 20 flagship actions, backed by EUR 1.2 billion in funding, to ensure that mental health remains on a par with physical health and is integrated across all policy areas.

On the food safety side, 2023 was also a productive year. In July, a key component of the [Farm to Fork Strategy](#) was delivered with a package of measures for the sustainable use of key natural resources, which will strengthen the resilience of EU food systems and farming.

New rules on the use of plants produced by certain new genomic techniques and modernised rules on plants and forest seeds will boost diversity, food security and EU competitiveness. Fixed targets to reduce food waste across the EU will help to lower the environmental impact of food production and consumption, while cutting costs for businesses and consumers. Finally, in December, our [animal welfare package](#) responded to citizens' concerns about the wellbeing of dogs and cats, while proposing enhanced EU rules for animals during transport.

These are just some of DG SANTE's achievements in 2023, which will directly contribute to Europeans living safer and healthier lives. I would like to thank all DG SANTE staff for the enthusiasm, professionalism and determination they show in their work, each and every day.

In 2024, DG SANTE will celebrate an important milestone – our 25-year anniversary as a DG! It will be an opportunity to look back with pride on the achievements of DG SANTE since it was created, while also reflecting on the challenges and opportunities that lie ahead. Health is our most precious commodity. In 2024, we must ensure that this mantra continues to catalyse our work.

Sandra GALLINA, Director-General of DG SANTE

THE DG IN BRIEF

DG SANTE contributes to two of the general objectives set out in [President von der Leyen's Political Guidelines](#) – [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. 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).

DG SANTE continues to play 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.

Protecting EU citizens' health also means managing EU health legislation which includes the rules governing the authorisation of pharmaceutical products and certification of medical devices, those applicable to 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**. In this area, the DG is responsible for designing, implementing and enforcing a coherent regulatory framework, which aims to ensure food safety, protect animals, and to respond to threats to human, animal and plant health along the food supply chain. EU funds are provided to co-finance measures directed at preventing and countering animal and plant diseases, to ensure food and feed safety, and to strengthen controls carried out by the Member States to ensure compliance with food chain requirements.

DG SANTE operates under the political leadership of the European Commissioner for Health and Food Safety, on the basis of multi-annual policies and financial frameworks.

The [EU4Health Programme](#), with a budget of EUR 735.8 million in the 2023 work programme (including EFTA credits), is the main financial instrument to fund the Union health initiatives. About 68% were attributed to DG SANTE and 32% to HERA. The EU4Health Programme continued to support the implementation of Union priorities stepping up preparedness against major cross-border health threats, such as the COVID-19 pandemic,



health-related urgencies due to Russia's unjustified and unprovoked war against Ukraine, the actions of the [European Health Emergency Preparedness and Response Authority \(HERA\)](#), [Europe's Beating Cancer Plan](#), the [Pharmaceutical Strategy for Europe](#), the comprehensive approach to mental health and the implementation of [European Health Union](#) legislation.

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, including the financing of EU Reference Laboratories (EURLs) and EU Reference Centres (EURCs), and relations with relevant international organisations. The total amended 2023 budget of the Food Safety strand of the Single Market Programme amounted to EUR 266 million for the elements implemented by DG SANTE and HaDEA. Due to unexpected high financial needs for the emergency measures (epidemics of African swine fever and avian influenza) with a limited total budget, the co-financing rate for veterinary and phytosanitary programmes had to be decreased by 60%. This reduced rate is implemented starting from 2023 programmes and will also be applied to the 2023 animal and plant health emergency measures.

DG SANTE is the lead DG for the [European Health and Digital Executive Agency \(HaDEA\)](#), which also works closely with DGs CNECT, DEFIS, GROW and RTD, and with HERA. HaDEA 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 lead 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 biocides activities. DG SANTE also has a seat on the Management Board of the [European Monitoring Centre for Drugs and Drug Addiction \(EMCDDA\)](#).

DG SANTE plans and reviews its main priorities and objectives annually, building its annual Management Plan around the resources available and any identified risks that may impact on its objectives. Bilateral meetings between the Director-General, her Deputy and Directorate and Unit managers, as well as weekly management meetings involving the Director-General and the Management Board are important monitoring activities.

At the end of 2023, DG SANTE had 723 statutory staff and 53 seconded national experts. 2023 saw the appointment of four Directors and the launch of the selection process of two others, as well as of a Deputy Director-General.

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 instruments 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 Treaties¹.

A. KEY RESULTS and progress towards achieving the Commission's general objectives and DG's specific objectives (executive summary of section 1)

1. A European Green Deal

Food and feed safety

In 2023, DG SANTE ensured proper implementation of the extensive *acquis* in the areas of food and feed safety, animal health and welfare, and plant health, taking a “**One Health**” approach which integrates human health, animal health, and environmental considerations into the decision-making process. At the same time, it achieved rationalisation of certain reporting obligations that result from that *acquis*, which may lead to considerable savings, and plans to further simplify and rationalise the reporting requirements and reduce related burden on businesses and/or national administrations.

Outbreaks of major animal diseases did not relent in 2023. The EU also faced outbreaks of the largest worldwide epidemic of [highly pathogenic avian influenza \(HPAI\) and African swine fever \(ASF\) in almost half of Member States](#). At the end of 2023 SANTE started preparatory work for the evaluation of the [EU Animal Health Law \(AHL\)](#), which governs the EU and Member States action in that area.

Regarding the [Plant Health Law](#) that DG SANTE manages, the Commission adopted [a proposal for its targeted amendment](#), which will bring further simplification and alleviation of administrative burden for businesses and national competent authorities.

Enforcement of food chain legislation is the responsibility of the Member States, tasked with official control duties in this area. Their work is governed by the [Official Controls Regulation](#). The regulation requires the Commission to carry out controls in Member States, to verify the compliance with control requirements, and in Third Countries, to verify the compliance or equivalence of their legislation and systems with official control requirements. During 2023, DG SANTE performed 84 controls in the Member States and 62 controls in non-EU countries that export to the EU, and issued recommendations in case of identified shortcomings.

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

Sustainable food systems – the ‘Farm to Fork’ Strategy

Russia’s war of aggression against Ukraine, a commodity price surge and the COVID-19 pandemic have all posed a risk to food security around the world. In this context, DG SANTE continued throughout 2023 to prepare a legislative proposal establishing a framework for a **Union sustainable food system**, with the objective to ensure long-term resilience and self-sufficiency of the EU food system.

In 2022, as part of the ambitions set in the EU Green Deal, Biodiversity and Farm to Fork strategies, the Commission proposed to overhaul the existing rules on the Sustainable Use of Pesticides with the worthy aim to reduce the risks of chemical plant protection products. In November 2023 the European Parliament voted to reject the [proposed Regulation on the sustainable use of plant protection products](#) (SUR) and closed its first reading. Taking into account that the Commission proposal had become a symbol of polarisation, that it had been rejected by the European Parliament and there was no progress anymore in the Council either, President Von der Leyen informed the European Parliament on 6 February 2024 that she would propose to the College of Commissioners to withdraw the proposal. The topic stays and to move forward more dialogue and a different approach will be needed. In the meantime, Directive 2009/128/EC establishing a framework to achieve the sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment remains in force.

The Commission proposed targeted amendments to the [Waste Framework Directive](#) to set targets for food waste reduction. The Commission also adopted a legislative proposal on plants obtained by certain new genomic techniques to support innovation in plant breeding and steer developments towards contribution to sustainability goals. Furthermore, it finalised legislative proposals for a revision of EU rules on the **protection of animals during transport** and for introducing new rules on the **welfare of dogs and cats**. The Commission also adopted [two legislative proposals on the production and marketing of plant and forest reproductive material in the Union](#), respectively.

In addition, the Commission adopted a [Regulation on procedures and criteria for identifying unacceptable co-formulants in plant protection products](#) in March 2023 and throughout the year numerous decisions on substances that can be used in the production of food to ensure consumer safety. The Commission adopted an implementing and a delegated act intended to improve inspections and **official controls on livestock vessels transported by sea** to verify the compliance with animal welfare rules.

International promotion of EU food safety standards

DG SANTE continued to promote the Farm to Fork Strategy internationally, on both bilateral and multilateral fora, seeking to build “green partnerships” with like-minded non-EU countries, and exploring the possibility to pursue the inclusion of Sustainable Food Chapters or provisions in the EU’s Free Trade Agreements.

DG SANTE actively contributed to the 28th UN Climate Change Conference (COP28) Declaration on sustainable agriculture, resilient food systems and climate actions and participated in debates on sustainability and healthy diets.

The relations with the Eastern Partnership countries were strongly affected by Russia's continuing war of aggression against Ukraine. DG SANTE actively participated in the establishment of the **Solidarity Lanes** supporting Ukraine to export grains and related products to other parts of the world.

2. Promoting our European Way of Life

In 2023, DG SANTE pursued its work of implementation of the European Health Union agenda, including through the funds of the EU4Health Programme. From the latter, over EUR 30 million were allocated to help people fleeing Ukraine in urgent need of mental health and trauma support.

In June 2023, The Commission published a [Communication on a comprehensive approach to mental health](#) and a call for [best and promising practices on mental health](#) was launched on the European Commission's Best Practice Portal. The 20 flagship actions of the Communication are being implemented via policy actions, projects and collaborative work.

Diminishing the impact of cancer in Europe

DG SANTE led on the implementation of the **Europe's Beating Cancer Plan** launched in 2021 to address cancer prevention, treatment and care. In 2023, the Commission launched 12 projects to implement it and on 23 January, the Commission launched the [European Cancer Imaging Initiative](#).

The Commission and the Organisation for Economic Co-operation and Development (OECD) published [the first Country Cancer Profiles](#) for all EU Member States, Norway and Iceland, as part of its Cancer Inequalities Register.

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

A flagship initiative for the implementation of the [Pharmaceutical Strategy for Europe](#) is the revision of the general **EU pharmaceutical legislation** and the EU legislation on medicines for children and rare diseases. In April, the Commission adopted the pharmaceutical package, with proposals for a new Regulation and a new Directive, Communication on the pharmaceutical reform and on measures addressing antimicrobial resistance and a Commission proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach.

The Commission also adopted a [Communication to address medicine shortages in the EU](#), to enable Member States to deploy joint efforts and pool resources to address future shortages.

In January 2023, the Commission adopted a proposal to give more time to certify medical devices to mitigate the risk of shortages that was [adopted by the Council on 7 March](#).

In 2023, 68 new medicines were authorised for human use, 37 included a new active substance, and 13 were authorised for treatment of rare diseases (of which 1 is an advanced therapy medicines). The Commission adopted 1159 decisions amending marketing authorisations (931 for medicinal products for human use, 228 for medicinal products for veterinary use) and 137 new designations for orphan medicines.

[A political agreement was reached](#) between the European Parliament and the Council of the EU on the **Regulation on fees charged by the European Medicines Agency**. The new Regulation was adopted in January 2024.

A political agreement was also reached between the European Parliament and the Council of the EU on the **Regulation on blood, tissues and cells**.

In 2023, a milestone was reached in implementation of the **EU-US Mutual Recognition Agreement** on inspections in the field of veterinary medicines. The EU [recognised](#) the US FDA as equivalent authority for veterinary products. At the same time, the US Food and Drug Administration (FDA) confirmed that sixteen national competent authorities have pharmaceutical Good Manufacturing Practices inspection capability, capacity and procedures for veterinary products, equivalent to those of the US.

Effective response coordination of serious cross-border health threats

On 5 May 2023, the World Health Organisation (WHO) officially announced the end of COVID-19 as a global health emergency. The [2023 State of Health Preparedness Report](#), drafted by SANTE, reflects and summarizes key actions for better preparedness.

The [Joint Procurement Agreement for medical countermeasures](#) has been paramount in fighting the COVID-19 pandemic. Its assessment was completed in 2023.

DG SANTE pursued the implementation of the 2017 **AMR Action Plan** laying out over 70 actions to fight antimicrobial resistance. In June 2023 [Council adopted the Commission's proposal](#) for a Recommendation to strengthen EU action against AMR.

More effective, accessible and resilient health systems

The legislative process regarding [the proposal for a Regulation on the European Health Data Space](#) has advanced in the European Parliament and the Council towards timely adoption of the regulation. In parallel, exploratory and preparatory activities for its implementation have been initiated.

DG SANTE contributed to the 2023 European Semester, including through the delivery of the thematic Annex on 'Health and Health Systems' in all 27 [Country Reports](#). Furthermore, [Country Specific Recommendations](#) addressing healthcare challenges were issued for 6 Member States.

DG SANTE appointed an Independent Body to conduct an evaluation of the first five years of operation of the 24 **European Reference Networks** (ERNs) for rare and complex diseases and 836 of their members. The results show that the ERNs system is suitable for its purpose and is delivering results for patients with rare diseases and their families.

The [Joint action HEROES on health workforce planning and forecasting](#) kicked-off in the first quarter of 2023.

B. Key performance indicators

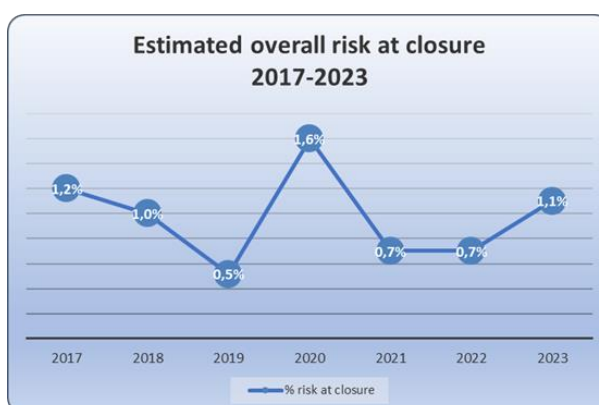
KPI1: Diminishing the impact of cancer in Europe

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 (31/12/2023)
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	Latest results available from 2014*

*Baseline (2014) results are the most up-to-date figures available, coming from CONCORD. A sustainable mechanism to obtain more timely results on survival rates is under investigation and will be integrated in the European Cancer Information System (ECIS) 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% for the total budget of EUR 589 million of payments made.



C. Key conclusions on internal control and financial management

In line with the Commission's Internal Control Framework DG SANTE has assessed its internal control systems during the reporting year 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 ethics, staff allocation and professional development, functions that are only partially under DG SANTE management. In addition, further attention is warranted to improve senior management's guidance on "missions, objectives and tasks", "change management" and certain elements of DG SANTE's control strategy. Please refer to annual activity report section 2.3 and Annex 8.2 for further details.

In addition, 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 the internal control deficiencies mentioned above. The following actions were and will be taken in this respect: an ethics and professional integrity awareness event for DG SANTE staff took place in June 2023, and further events will be organised in 2024 in close co-operation with OLAF, IDOC and DG HR; with its new organisational structure as of 1 October 2022, DG SANTE invested heavily in filling the many vacant senior management posts of which 30% remained vacant in 2023; DG SANTE's update of its internal control strategy is postponed to 2024 to take the new corporate guidelines into consideration. The Director-General, in his capacity as Authorising Officer by Delegation, has signed the Declaration of Assurance.

D. Provision of information to the Commissioner(s)

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 Kyriakides, responsible for Health and Food Safety.

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

Food and feed safety, animal health and welfare, and plant health contribute significantly to the European Green Deal. In 2023, DG SANTE ensured proper implementation of the extensive *acquis* in these areas, taking a “One Health” approach which integrates human health, animal health, and environmental considerations into the decision-making process. The application of the One Health approach was also particularly strengthened by the fact that DG SANTE is the partner DG of four EU decentralised agencies providing scientific advice

related to the protection of human and animal health and the environment, including EFSA.

On 13 November a “One Health” conference bringing together high-level experts, stakeholders and international organisations successfully provided a comprehensive platform for knowledge sharing and collaboration on topics such as climate change, environment and health, surveillance and early warning systems, and antimicrobial resistance. It was positively received by over 9,000 followers online and on social media.

Simplification of the existing regulatory framework was also pursued whenever possible. DG SANTE has contributed to President von der Leyen's announcement of a target of 25% reduction of reporting obligations resulting from the EU *acquis*. We achieved rationalisation of reporting obligations, in particular for national authorities in the Member States, related to eradication programmes for animal health and plant pests and on TSE, trichinella and food irradiation. The reporting rationalisation on trichinella may lead up to annually EUR 1 million savings for slaughterhouses. For more information on simplification initiatives (see Annex 2, Result Indicators 1.1.D and 1.1.E). In addition, DG SANTE has prepared a plan to simplify and rationalise the reporting requirements and reduce related burden on businesses and/or national administrations, without undermining the policy objectives. The plan includes a list of concrete measures planned for 2024 and beyond to progress towards the goal of 25% reduction of such burden.

In 2023, 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, thus further consolidating European consumers' confidence. Revisions of food hygiene requirements and guidance contributed to the safety of innovative products (e.g. aged meat) and to a more harmonised and fair implementation. New requirements were introduced on the surveillance of methicillin-resistant

Staphylococcus aureus (MRSA) in pigs, a zoonotic agent causing many healthcare- and community-associated infections that are difficult to treat in humans as they are resistant to multiple antibiotics.

Ensuring animal health and managing and isolating outbreaks of major animal disease. In 2023, DG SANTE continued to actively pursuing [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, there was an increase of over 26% in disease-free statuses obtained by Member States in 2023, as anticipated in the planning, based on the compulsory eradication programmes of the Animal Health Law. In July an [Implementing Regulation](#) was adopted on animal diseases removing non-essential reporting elements and clarifying certain key definitions.

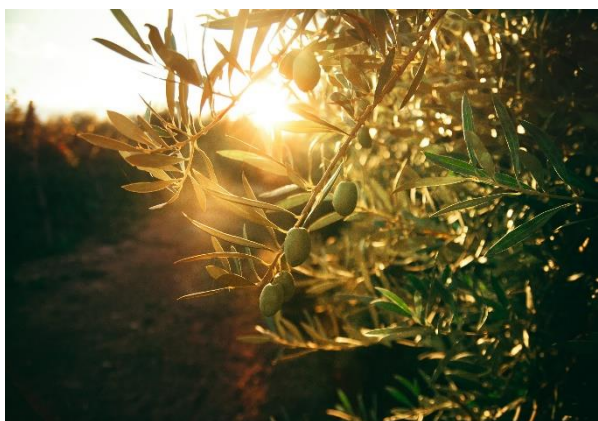
Outbreaks of major animal diseases did not relent in 2023. The EU also faced outbreaks of the largest worldwide epidemic of [highly pathogenic avian influenza \(HPAI\)](#) and [African swine fever \(ASF\) in almost half of Member States](#), and a few Sheep Pox and Goat Pox outbreaks. These required continuous efforts to ensure effective control and eradication to stabilise the disease(s) situation by the end of the year.

This was achieved through the adoption by the Commission of special control measures for ASF and emergency measures for HPAI and sheep and goat pox, and the regular and swift amendments of the relevant regionalization measures to minimise impacts on non-affected regions. Specific rules for vaccination against the most severe transmissible animal diseases, including HPAI were introduced in February as an additional tool to complement the effective control, and where relevant, prevention of diseases. The European Food Safety Authority was tasked with assessing the current availability of vaccines against HPAI for poultry, to help design potential vaccination strategies and the surveillance following the vaccination, enabling safe movements of animals and products from establishments and zones where vaccination has taken place to continue. (See details on specific measures in Annex 2).

Due to the unprecedented extent of the outbreaks, the Union's ability to co-finance the costs incurred by the Member States to implement emergency plans was put to a severe test; in order to ensure such co-financing could continue in the coming years, in December 2022 the Commission submitted to the Member States a decision to temporarily reduce the rate of the Union's co-financing by 60%.

At the end of 2023 SANTE started preparatory work for the evaluation of the [EU Animal Health Law \(AHL\)](#), which provides the regulatory framework to fight transmissible animal diseases, while continuing to ensure its smooth implementation. Furthermore, DG SANTE supported both Member States and the EU's main trading partners to ensure a smooth implementation of the rules, notably through the adoption of new implementing regulations aimed at alleviating undue administrative burden. For instance, the removal of non-essential reporting elements on animal diseases, which will result in substantial reduction of reporting obligation for Member States with up to 80% reduction of indicators for the ongoing and upcoming compulsory eradication programmes.

DG SANTE continued to support the correct implementation of EU requirements in the Union to prevent and control major animal health diseases by completing audits on African Swine Fever and Avian Influenza in Member States. In addition, a workshop was organised on 4 and 5 December 2023 in to support Member States in implementing EU requirements on contingency planning for animal health diseases.



Preventing plant pests. New threats emerging from climate change and globalisation have increased the risk of plant pest infestations. DG SANTE is in charge of the implementation of the [Plant Health Law](#) to protect crops, fruits, vegetables, flowers, ornamentals and forests against new pests and diseases includes rules on the movement of plants and plant products within the EU, and a strict regime for imports of the same

that might host dangerous pests. Work continued to grant science-based derogations to the provisional ban on imports of a list of high-risk plants (8 implementing acts were adopted in 2023). A new measure for the eradication and containment of *Popillia japonica* was adopted. Three existing emergency measures were updated to take account of the latest science (for Tomato brown rugose fruit virus related to tomato and pepper seeds, *Spodoptera frugiperda* on many crops and *Xylella fastidiosa* on many fruit plants and ornamental plant species. With the purpose to rationalise the reporting requirements, the Commission adopted [a proposal for targeted amendment of the Plant Health Law](#) together with its Work Programme 2024 (For details on specific measures see Annex 2).

The reports submitted by Member States on the implementation of the 24 phytosanitary programmes approved by the Commission in 2022 for a total amount of 20 million Euro, show that Member States take the necessary measures to survey and eradicate quarantine pests in line with the plant health Regulation.

Ensuring market access to safe substances and products. In 2023, DG SANTE continued to oversee the authorisation and approval procedures for foods and for substances or products used in food and feed production and processing and authorised a range of substances whose safety was positively assessed. Such substances include food and feed additives, food flavourings, novel foods, vitamins and minerals added to food for specific groups, substances used in plastic food contact materials, active substances used in plant protection and biocidal products, genetically modified organisms, and veterinary medicines. DG SANTE also continued to manage the establishment of statutory limits on the presence of certain substances, such as maximum residue levels for pesticides, or maximum levels for contaminants in food and feed. New limits were adopted for inorganic arsenic to reduce consumer exposure to these carcinogenic contaminants and thus contribute to the objectives of the [Europe's Beating Cancer plan](#). (For details on specific decisions taken see Annex 2).

Based on comprehensive safety assessments carried out by the European Food Safety Authority and the European Chemicals Agency, the Commission proposed the renewal of

approval of glyphosate for 10 years subject to appropriate conditions and restrictions, such as a prohibition of pre-harvest use as a desiccant and measures to protect non-target organisms. No qualified majority was reached by Member States, neither in favour nor against the Commission's proposal in the Standing Committee on Plants, Animals, Food and Feed on 13 October 2023, nor at the Appeal Committee on 16 November. In line with its legal obligation to take a decision before 15 December 2023, when the previous approval period expired, the Commission therefore adopted on 28 November an Implementing Regulation renewing the approval.

In October, based on a scientific assessment by EFSA, the Commission set new reduced limits for nitrites and nitrates as food additives. These new limits aim to keep consumers safe from infection by pathogenic bacteria such as *Listeria* and *Salmonella* while better protecting them from carcinogenic substances. The Commission also started discussions with Member States on the follow-up to the latest EFSA opinions indicating concerns on the safety of Bisphenol A (BPA - published in 04/23) and smoke flavourings (11/2023). In February 2023, the Commission adopted a Regulation, based on an assessment published by EFSA, to lower existing Maximum Residue Levels (MRLs) for two chemicals that belong to the group of neonicotinoid pesticides: clothianidin and thiamethoxam. These substances pose a high risk to bees and contribute to the decline in pollinators, which is a global problem. The new rules build on the ban on their outdoor use in the EU (introduced in 2018) by reducing the permissible residues to the lowest level that can be measured with the latest technologies. These rules will apply as from February 2026 to products produced in the EU and to imported food and feed products.

Performing effective, efficient and reliable controls. Enforcement of food chain legislation is the responsibility of the Member States, tasked with official control duties in this area. Their work is governed by the [Official Controls Regulation](#). The regulation requires the Commission to carry out controls in Member States, to verify the compliance with control requirements, and in Third Countries, to verify the compliance or equivalence of their legislation and systems with official control requirements. During 2023, DG SANTE performed audits, in Member States (84 controls) and non-EU countries (62 controls) that export to the EU and issued recommendations in case of identified shortcomings.

At the end of 2023, verified corrective actions had been taken by the Member States in response to 69% of the audit recommendations addressed to them in the period 2019-2021 (See Annex 2, Result indicator 1.1.C). This is below the 2022 interim target of 75%. The indicator based on a three-year rolling period would naturally oscillate at around 70%. To reach a closure of recommendations above 70%, Member States would require more time (a longer rolling period). All recommendations remaining open at the end of 2023 continue to be monitored by DG SANTE for progress.

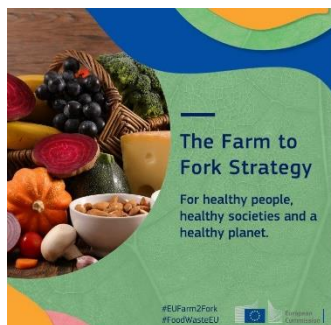
DG SANTE publishes the reports of the controls on its website. DG SANTE also published overview reports summarising situation in a certain sector based on the controls carried out. In 2023, DG SANTE published six overview reports on: food fraud, the outbreaks of *Xylella fastidiosa* and of tomato brown rugose fruit virus, live bivalve molluscs, the welfare of laying hens and plant pest outbreaks Member States reporting 2020/2021. DG SANTE also

publishes an annual report on the official controls in the EU. In 2023, the annual report covered year 2021.

In 2023, DG SANTE further complemented and updated the legal framework on official controls with rules on border checks.

Maintaining well-developed rapid alert systems. Effective official controls by and in the Member States, and risk management decisions by the Commission, also rely on DG SANTE's implementation and management of the Information Management System for Official Controls (IMSOC), the comprehensive IT system that integrates several IT applications used by the Commission and Member States to implement food chain requirements (e.g. Trade Control and Expert System (TRACES) and certain EU alert systems like RASFF and EUROPHYT).

In 2023 DG SANTE launched the renewal of its collaborative IT platform "iRASFF" to support the Alert and Cooperation Network which will be implemented in policy areas in which it was previously not yet active such as plant health. In addition, the Animal Disease Information System (ADIS) was further developed by facilitating data exchange with other databases, and by simplifying the notification procedure for animal diseases through a single entry point for the legally required double notification to both the World Organisation for Animal Health (WOAH) and to the Commission.



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

Throughout 2023 continued the preparation of a legislative proposal establishing a framework for a Union sustainable food system in close collaboration with DG AGRI, DG ENV and DG MARE. Moreover, together with DG JRC and other Commission services, DG SANTE continued working on a monitoring framework of the

Farm to Fork strategy in view of publishing a dashboard in 2024. The objective is to monitor the transition to a sustainable food system so that it operates within planetary boundaries, including progress on the targets of the Farm to Fork Strategy and overall reduction of the environmental and climate footprint of the EU food system.

Russia's war of aggression against Ukraine, a commodity price surge and the COVID-19 pandemic have all posed a risk to food security around the world. While the resilience and self-sufficiency of the EU food system have ensured that the availability of food in the EU is not at risk, the Commission continues to take measures to prepare for and respond to potential threats to global food supply and food security. DG SANTE was actively involved in the work led by DG AGRI to prepare [Recommendations on ways to improve the diversity of sources of supply](#) and the [guidelines for crisis communication on food supply and food security](#) which were adopted by the expert group on the European Food Security Crisis Preparedness and Response Mechanism (EFSCM) on 7 July. Established in 2022, the EFSCM aims to improve cooperation between the public and private sectors and evaluate risks when crises arise.

DG SANTE also actively contributed to the work led by DG AGRI to assess the amendments by Member States to their National Strategic Plans (NSPs) for the Common Agricultural Policy (CAP) as regards certain Farm to Fork objectives.

Reducing dependency on and promoting the sustainable use of pesticides.

During 2023, the co-legislators continued discussions on the [proposal for a Regulation on the Sustainable Use of Pesticides \(SUR\)](#) revising the Sustainable Use Directive adopted by the Commission in June 2022. The proposal aims to reduce the risks and impacts of pesticide use on human health and the environment, translating into action the EU's commitment to halt biodiversity loss and to improve the availability of sound data and statistics on the use of pesticides for evidence-based policy making. It puts forth legally binding targets at EU and national level to reduce by 50% the use and the risk of chemical pesticides and the use of the more hazardous pesticides by 2030.

In July 2023, the Commission published its response to the request of the Council for additional data on the impact of the proposal. The additional information that the Commission provided confirms that the pesticide reduction goals of the Commission proposal do not threaten food security, despite the negative shorter-term impacts of Russia's war of aggression against Ukraine, and that failure to deliver on the pesticide reduction objective now would have long-term and potentially irreversible effects on EU food security in the future.

On 22 November 2023 the European Parliament voted to reject the SUR proposal on first reading. President Von der Leyen informed the Parliament early February 2024 that she would propose to withdraw the proposal. Throughout 2023, DG SANTE continued to work with and support Member States in the implementation of the current rules (the Sustainable Use of Pesticides Directive), including through BTSF trainings to exchange best practices specifically on Integrated Pest Management (IPM) and to perform fit-for-purpose risk assessments of microorganisms used in plant protection products. In this context, the annual update on the [targets for reduction of pesticides](#) published in July showed, by the end of 2021, a reduction of chemical pesticides of 33% and a reduction of more hazardous pesticides of 21% at EU level. 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 three Member States.

In addition, DG SANTE continued in 2023 to actively work towards reducing dependency on pesticides and improving the take-up of low-risk and non-chemical alternatives for plant health protection, guided by the Farm to Fork targets. To increase the ability of farmers to protect their crops by substituting biological alternatives for chemical pesticides, DG SANTE worked with Member States and EFSA to implement the new data requirements for microorganisms in plant protection products with a view to realising the potential of faster and easier submission and processing of dossiers via studies and guidance documents. Training and capacity building was also provided for Member States – among others via BTSF training and awarding of grants under the Single Market Programme.

DG SANTE also progressed with a number of actions to facilitate approvals for low-risk chemical active substances (such as pheromones and plant extracts) and the authorisation of products containing them, e.g. via EU guidance or adaptation of data requirements and assessment criteria.

Furthermore, a Regulation on procedures and criteria for identifying unacceptable co-formulants in plant protection products was adopted in March 2023 and a work programme for the assessment of safeners and synergists was prepared and discussed with the Member States in December 2023.

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 competent authorities (subject to certain conditions) to perform such work. Such agreements were signed with 15 Member States at the end of 2023 both for the areas of pesticides and biocides.

Reducing the use of antimicrobials in animals to contribute to the fight against AMR. In 2023, 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. The latest [annual report on European Surveillance of Veterinary Antimicrobial Consumption](#) shows that the overall sales of veterinary antibiotics decreased by 53% from 2011 to 2022, bringing us closer to the EU Farm to Fork target. In only 4 years (2018-2022), overall EU sales reached over half of the target (see the relevant result indicator in the Annex). Implementing rules for the new EU Regulations on Veterinary Medicinal Products and on Medicated Feed include core measures to combat AMR. The Commission has already controlled the effective implementation of the Veterinary Medicinal product Regulation, with a particular focus on the prudent use of antimicrobials (2 controls). Commission Delegated Regulation (EU) 2023/905 was published in May 2023. It supplements Article 118 of Regulation (EU) 2019/6 as regards the prohibition of the use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union. Significant progress has been made for the implementation of Regulation (EU) 2023/905, both on the amendment of the relevant import certificates and on the assessment of written guarantees from third countries that would be the basis for their inclusion in the list of approved third countries. In addition, the Commission has made significant progress in the discussions with Member States concerning the delegated act that will establish appropriate measures to ensure the effective and safe use of veterinary medicinal products – including antimicrobials – authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals.

Fostering the use of innovative and more sustainable feedstuffs. To reduce the environmental and climate impact of animal production, DG SANTE continued to work to facilitate the placing on the market of sustainable and innovative feed additives which are efficacious and safe for the target species, consumers, and the environment. In particular,

an urgent provisional authorisation of four cobalt-based additives was granted in July 2023 with a view to avoid negative effects on the welfare of ruminants, horses and rabbits deriving from an interruption of the previous authorisation of the use of these additives. The evaluation of the Feed Additives legislation, Regulation (EC) No 1831/2003, has greatly advanced in 2023 pending only the publication of its results.



Reducing food loss and waste. The European Union is [committed 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 order to accelerate the EU's progress towards the global target, and in line with the Farm to Fork Strategy action plan, the Commission, proposed in July targeted amendments to the

[Waste Framework Directive](#) which would introduce legally binding targets to reduce food waste across the EU. If adopted by the co-legislators, this would commit the Member States to take the necessary measures to reduce food waste by the end of 2030 by 10% in processing and manufacturing, and by 30% (per capita), jointly at retail and consumption levels (restaurants, food services and households).

DG SANTE organised the first-ever [citizens panel](#) convened by the Commission to contribute to the development of a European political and legislative initiative. It reflected on ways to step up action to reduce food waste in the EU and the report of February 2023 included 23 recommendations to strengthen cooperation in the food value chain; encourage food business initiatives; and support consumer behavioural change. These recommendations helped inform the preparation of the amendment of the Waste Framework Directive proposed in July. In collaboration with DG COMM, DG SANTE organised a joint meeting of the citizens' panel and the [EU Platform on Food Losses and Food Waste](#), held on 7 November, to provide feedback to citizens on their recommendations.

DG SANTE supported Member States in the implementation of the EU provisions on food waste measurement in cooperation with ESTAT. It oversaw the delivery of a ["best practice" compendium](#) in consumer food waste prevention by the European Consumer Food Waste Forum, an EU pilot project managed by the JRC. The compendium of tools, best practices and recommendations was launched at an [event in the European Parliament](#) on 29 June 2023.

DG SANTE actively contributed to international work in food loss and waste prevention, including through the [Champions 12.3 coalition](#), and the participation in G7 and G20 networks, the UN Food System Summit follow-up (UN Stocktaking Moment), and COP28. DG SANTE participated as well in a high-level event organised by FAO and UNEP in order to mark the 4th edition of the International Day of Awareness of Food Loss and Waste held annually on 29 September.



Ensuring a sustainable food production that improves the welfare of animals.

Good treatment of animals is an integral part of sustainable food production. Following the 2022 [Fitness Check evaluation of the animal welfare legislation](#) (five EU Directives and two EU Regulations, covering animal welfare on farms, during transport and at the time of killing), and as announced in the Farm to Fork Strategy, DG SANTE, based on a series of EFSA scientific opinions, continued the work on the impact

assessment to revise the EU animal welfare legislation, including by carrying out stakeholder consultation. This included the work to follow-up from the Commission's [answer to the European Citizens' Initiative "End the cage age"](#).

The Commission finalised two legislative proposals based on that work, one for a revision of EU rules on the protection of animals during transport, and one introducing new rules on the welfare of dogs and cats, both of which were adopted by the Commission on 7 December 2023. These initiatives were promoted with a substantial press package, audio-visual material and a strong presence on social media which proved to be very popular, particularly for the cats and dogs initiative.

The proposal on transport aims to improve the welfare of animals and ensure a better functioning of the internal market in this area, by reducing long journeys, increasing space allowance, better protecting vulnerable animals and animals exported to third countries, avoiding exposure of animals to extreme temperatures, and facilitating enforcement through digitalisation.

The proposal on dogs and cats will establish, for the first time, uniform EU animal welfare standards for the breeding, housing, and handling of dogs and cats in breeding establishments, pet shops and shelters and competence of animal caretakers in these establishments. The traceability of dogs and cats will also be reinforced through mandatory identification and registration in national databases to prevent illegal trade and better control animal welfare conditions in the establishments.

As regards the protection of animals kept for farming purposes and their protection at the time of killing, the Commission is now reflecting on and carefully assessing important aspects, including the related costs and the appropriate length of the transition period. It is important to seek the support of all involved to make these proposals a success.

DG SANTE's management of the [EU Animal Welfare Platform](#) directly supported the implementation and revision of the legislation, especially through the 6 subgroups created in 2022 to provide expert input.

In February 2023, the Commission adopted an implementing and a delegated act intended to improve inspections and official controls on livestock vessels transported by sea to verify

the compliance with animal welfare rules. The implementing regulation provides for an electronic database where Member States must record the results of inspections performed on livestock vessels, as well as the onboard presence of an official veterinarian during a vessel's first journey to make sure the equipment is in good working order. Seaports must also have a control post in their vicinity to facilitate resting of animals should this be necessary.

In March 2023, DG SANTE published a report on controls linked to the protection of the welfare of laying hens at all the stages of production in the European Union and completed a series of animal welfare audits in Member States to ensure the welfare of calves transported over long distances, and launched two audit series on the welfare of fish and of cattle for beef production.

In 2023, DG SANTE continued to ensure the supervision of the three existing Animal Welfare Reference Centres and selected a new Reference Centre for the welfare of fish in aquaculture.

In 2023, a pilot project on Best Practices for alternative egg production systems has been finalised, and a final communication and dissemination event was organised, thus providing further technical advice for farmers to phase out cages for laying hens reverting to more welfare friendly production systems.



The Commission [replied to the European Citizens' Initiative \(ECI\) 'Fur Free Europe'](#) which calls for an EU-ban on fur farming and on the marketing of farmed fur and fur products in the EU. In its [Communication](#) adopted as part of the animal welfare package on 7 December, the Commission informed that it requested EFSA to produce by March 2025 a scientific opinion on the welfare of farmed fur animals, and that it will evaluate by March 2026 which follow-up

to give to the ECI request based on that EFSA opinion.

Moreover, DG SANTE continued to support Member States in harmonising the implementation of legislation on the transport of animals by coordinating the work of the informal [Commission Expert Group of Liaison bodies for the protection of animals during transport](#).

Fighting against agri-food fraud. In 2023, DG SANTE continued to work with the Member States on actions directed at combating agri-food fraud. In March 2023, the results of the EU coordinated action ["From the hives"](#) involving the JRC, OLAF and national authorities were published. It was followed in December by the publication of the results of coordinated controls targeting the illegal trade of cats and dogs. Both actions helped identifying recurrent fraudulent practices and resulted in administrative and judicial proceedings by the Member

States, and led to the adoption of corrective measures of honey marketing standards and animal welfare.

Empowering consumers to make sustainable and healthy food choices through the provision of food information. In 2023, DG SANTE continued to work on the implementation of the existing food information rules, including through national notifications and the approval of nutrition and health claims made on food products. Work on the maximum amounts of vitamins and minerals that can be added to these foods and the implementation of the Regulation on Food for specific groups continued.

Supporting innovation in the food chain, especially via the promotion of novel food, plant reproductive materials and innovative techniques. DG SANTE continued to facilitate new opportunities under Horizon Europe to deliver innovative knowledge and data to support the objectives of the Farm to Fork Strategy e.g. on food waste, finding alternatives to antimicrobials and synthetic chemical pesticides, and improving access to healthy diets.

DG SANTE authorised 2 insect species as novel foods in 2023, in addition to 17 other novel foods.



EUs agri-food production was supported in 2023 by the introduction of 1750 new varieties of agricultural and more than 1150 new varieties of vegetable species in the Common Catalogues.

On 5 July 2023, the Commission adopted [two legislative proposals on the production and marketing of plant and forest reproductive material in the Union](#), respectively. The proposed Regulation on plant reproductive material (PRM) would replace 10 marketing Directives with one single act. The PRM Regulation maintains the principle that varieties have to be registered and PRM certified before they can be placed on the market. Once adopted, the new legislation will increase the diversity of PRM on the market and of cultivated crops in the fields, support organic production, and provide more choice for amateur gardeners.

New improved plant varieties, which are for instance disease resistant, drought tolerant or use less fertilisers, are central in addressing the challenges of climate change and improving the sustainability of the agri-food chain. Therefore, also on 5 July, the Commission adopted [a proposal for a new Regulation on plants produced by certain new genomic techniques](#). The main objectives of the proposal are to maintain a high level of protection of health and the environment; to steer developments towards contribution to sustainability goals in a wide range of plant species, especially for the agri-food system; and to create an enabling environment for research and innovation, especially for SMEs. The proposal covers plants that contain genetic material from the same plant (targeted mutagenesis) or from crossable

plants (cisgenesis, including intragenesis); transgenic plants (which contain genetic material from non-crossable species) will remain subject to the GMO legislation as it stands today.

At the end of 2023 DG SANTE launched preparatory 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. The evaluation will also cover the Community Plant Variety Office (CPVO) managing these rights.

Improving the regulatory framework on Food Contact Materials (FCM). FCMs, including food packaging, play a key role in food system sustainability, and a revision of the EU legislation on FCMs is an important part of the Farm to Fork Strategy, as well as other core Commission commitments such as the Chemicals Strategy for Sustainability (CSS). Throughout 2023, DG SANTE continued its work on an impact assessment.

DG SANTE also continued to work on the implementation of [Commission Regulation \(EU\) 2022/1616](#) on recycled plastic materials and articles intended to come into contact with foods, which came into force in October 2022. This has included preparing decisions for over 230 authorisations of mechanical PET plastic recycling processes. 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

DG SANTE steers the Commission's position on promoting internationally the EU policy models on safety and quality standards and sustainable food systems, and coordinates Member State input to ensure policy coherence between our internal policy actions and external engagement on the global stage. Our current focus is on the ambitious international dimension of the Green Deal and Farm to Fork Strategy. This work contributes to the EU's achievement of certain UN Sustainable Development Goals (SDG), especially SDG 2 *Zero hunger*, SDG 3 *Good health and well-being*, and SDG 12 *Responsible consumption and production*.

DG SANTE continued to promote the Farm to Fork Strategy internationally, seeking to build “green partnerships” with like-minded non-EU countries, and exploring the possibility to pursue the inclusion of Sustainable Food Chapters or provisions in the EU's Free Trade Agreements. The international outreach and buy-in of the Strategy represent a major challenge whose outcome ultimately depends on external factors as non-EU countries may not share the ambitions of the Green Deal or may have different views on how to approach this goal.

Improving multilateral relations. The EU is the largest exporter and third largest importer of food in the world, with a well-recognised and respected framework of food safety legislation. In 2023, DG SANTE continued to promote food safety and quality standards, including through the BTSF programme and the Commission's Foreign Policy and Trade Initiatives, and, in line with the Farm to Fork Strategy, the global transition to sustainable food systems, through its work in multilateral fora and international standard setting bodies.

DG SANTE represented the EU in the World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) Committee meetings where it continued to promote sustainability and the One Health approach, particularly during the implementation of the Work Programme stemming from the SPS Declaration of the 12th Ministerial Conference of the WTO.

DG SANTE promoted and supported relevant initiatives of the Food and Agriculture Organization (FAO), World Health Organization (WHO) and other UN agencies on the implementation of their food safety strategies by pursuing the application of the One Health approach, and the importance of fighting against antimicrobial resistance, climate change and biodiversity loss. DG SANTE has agreed to finance four multi-annual projects in support of sustainability, healthy diets and scientific advice provided by FAO and WHO agencies. Furthermore, DG SANTE actively engaged with the UN agencies in the 2023 UN Stocktaking Moment and played a central role by sharing best practices.

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 2023 DG SANTE represented the EU in the Codex Alimentarius on the occasion of the Codex's 60th anniversary, advocating above all for due consideration of the One Health approach and of sustainability aspects in the development of Codex standards. More than 500 new and revised Codex standards (including MRLs for pesticides, Maximum Limits for contaminants and food additive provisions) were adopted. The Codex "Guidelines for the Safe Use and Reuse of Water in Food Production and Processing" provides recommendations on the safe use of water for food production in a global context of water scarcity.

DG SANTE actively participated in and contributed to the intersessional activities under the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety, as follow-up to the CBD Conference of the Parties (COP-15) and Cartagena Protocol meeting of the Parties (COP-MOP10) in 2022, and in preparation of meetings of the Conferences of the Parties scheduled in 2024. During COP-15, DG SANTE participated to the discussions of the aspects related to biotechnology in the Global Biodiversity Framework, as well as to synthetic biology. Discussions related to the Cartagena Protocol focused on risk assessment & risk management, compliance, and capacity building.

DG SANTE actively contributed to the 28th UN Climate Change Conference (COP28) Declaration on sustainable agriculture, resilient food systems and climate actions and participated in debates on sustainability and healthy diets.

Improving bilateral trade relations. The EU's external trade requires strong engagement with trade partners to ensure the relevant safety requirements are met to protect health and prevent trade disruption. Trade policy is a key instrument to promote the EU Sanitary and Phytosanitary (SPS) system and the Farm to Fork Strategy. DG SANTE continues to cooperate with partners in a horizontal way, through trade agreements, the Partnership instruments and training programmes.

DG SANTE continued to lead negotiations on SPS in the Free Trade Agreement negotiations underway. In 2023, the negotiation on the SPS Chapters were closed with Australia whilst progress was achieved with the resumed FTA negotiations with India.

On SFS, the Chapter was almost closed with India, and good progress was achieved with Indonesia. DG SANTE also devoted substantial efforts with the re-opening of SPS/SFS negotiation with Thailand and the preparation of the resumed FTAs with the Philippines and Malaysia.

On the UK, the work focused on the implementation of SPS Chapter in the EU-UK Trade and Cooperation Agreement (TCA) and in particular to receive full clarity on the implementation of the UK Border target operating model (BTOM) defining the controls and certification requirements for the EU exports to the UK.

DG SANTE also worked on the successful negotiations for a number of enlargement-related dossiers. DG SANTE coordinated the screening meetings on Chapter 12 and Chapter 28 with Albania and Northern Macedonia and also contributed to the enlargement reports for all candidate and potential candidate countries based on which the Council endorsed in 2023 the start of the accession negotiations with Ukraine and Moldova and the granting to Georgia of the status of candidate country.

The DG continued to pursue good bilateral SPS relations with key commercial partners. In particular DG SANTE concluded with Japan the project regarding the mutual recognition of animal health related to the High Pathogenic Avian Influenza, which will have a substantial benefit for the EU trade. Progress was recorded on the African Swine Fever part of the same project.

DG SANTE succeeded to reopen the dialogue with US on Food Safety issues and the first EU-US Food Safety Working Group took place in 2023, being an excellent communication channel with the US administration on food safety matters. During the EU-US Animal Health Technical Working Group, DG SANTE took the opportunity to clarify the EU HPAI vaccination strategy. The meeting also allowed to the EU to express openly its concerns in relation to the decision taken by the US to discontinue the import of avian commodities derived from HPAI-vaccinating Member States.

DG SANTE strengthened the good co-operation in the Sanitary and Phytosanitary (SPS) area with a fruitful dialogue during the latest SPS Joint Management Committee (JMC) with Canada, where Parties agreed to continue ensuring appropriate follow-up on the action points and work plan.

DG SANTE succeeded in re-establishing the dialogue with Brazil on SPS matters by meeting, after several years, the SPS Consultation Mechanism in June 2023. Following this meeting, several audits to the country were scheduled and working meetings were organised. Furthermore, the fruitful dialogue with Chile continues and it allows to maintain and increase a safe trade flows even in case of outbreaks.

Moreover, DG SANTE succeeded to have major records with Korea in terms of trade, by achieving the final stage on longstanding files: the recognition of the EU regionalisation principles and the opening of Korean market for French and Irish beef. In addition, DG SANTE signed an administrative arrangement with Korea concerning e-certification. DG SANTE achieved SPS deliverables also with Vietnam (regionalisation and prelisting), with Singapore

(regionalisation and acceptance of vaccination against HPAI in some EU MS) and Saudi Arabia (lift of the ban due to BSE for the whole EU). Most of EU market access applications were concluded with Singapore.

The relations with the Eastern Partnership countries were of course strongly affected by Russia's continuing war of aggression against Ukraine. DG SANTE actively participated in the establishment of the Solidarity Lanes supporting Ukraine to export grains and related products to other parts of the world. In addition to frequent ISG-meetings and those of the UA-platform with representatives from Poland, Slovakia, Hungary, Romania, Bulgaria and Ukraine, DG SANTE also participated in two Commission missions to Poland and Romania/Moldova to take stock of the situation on the ground.

General Objective 2: PROMOTING OUR EUROPEAN WAY OF LIFE

European Health Union. In 2023, DG SANTE pursued its work of implementation of the European Health Union agenda, notably in the areas of mental health, the fight against cancer, serious cross-border threats to health, the Pharmaceutical Strategy and digital health.

Support to Ukraine. As the Russian aggression against Ukraine entered its second year, DG SANTE continued its activities in the area of public health to help address the devastating consequences for the physical and mental health of Ukrainian civilians. 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 also continued to work with health ministries through the EU Health Security Committee, which has been meeting regularly to analyse the situation and identify how to best provide support. This work complements a dedicated European system for swift transfers of persons in need of medical care among EU Member States.



EU solidarity with Ukraine
in the area of health

- Medical evacuations
- Psychosocial first aid
- Access to healthcare for displaced persons
- EU4Health association agreement



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. More specifically, a EUR 31.19 million contribution agreement was signed in June 2022 with the International Federation of Red Cross and Red Crescent societies to help people who have fled Ukraine or are displaced within Ukraine deal with the trauma they have suffered and offer them mental health and psychosocial support. Ukraine's displaced people are also the focus of a EUR 3 million call for proposals from non-governmental organisations for best practices to

improve mental health and psychological well-being in the migrant and refugee populations. All four projects were launched in 2023. Two contribution agreements have been signed with International organisation for migration (IOM) and WHO (EUR 4 million in total) for improving

access to healthcare for refugees and people displaced from Ukraine benefitting of temporary protection in Member States. 10 countries are supported. The project began on 10 October 2023 and will last 24 months. The Communication on a comprehensive approach to mental health, adopted in June 2023, specifically addresses vulnerable groups, such as displaced people from Ukraine. One of its flagships is a multidisciplinary training and exchange programme, which will include specific modules related to the psychological needs of those fleeing the war in Ukraine as well as those living in Ukraine. The project started in January 2024.

In July 2022, the European Commission signed an agreement associating Ukraine to the EU4Health programme, under which Ukrainian representatives participate in the EU4Health Programme governance. Ukrainian public and private entities receive already funding through 12 projects, which cover, among other, antimicrobial resistance, cancer, cardiovascular diseases, diabetes and other non-communicable diseases, with a total budget of about EUR 3.4 million.

Comprehensive initiative on mental health. Before COVID-19, 1 in 6 Europeans already suffered from mental health issues, a situation that has only worsened since the pandemic. The cost of doing nothing to address this crisis has been estimated at EUR 600 billion a year. In June 2023, The Commission published a [Communication on a comprehensive approach to mental health](#) based on three guiding principles: 1) adequate and effective prevention; 2) access to high quality and affordable treatment; and 3) reintegration into society after recovery. In the preparatory phase, a youth policy dialogue was held with Commissioner Kyriakides to gather the views of those affected by mental health issues. It took place in the context of the European Year of Youth and as a follow up to citizens' requests at the Conference on the Future of Europe. In addition, a high-level conference in Brussels brought together hundreds of representatives from the EU institutions, national governments, international organisations and other interested partners to listen to testimonials, exchange information and good practices on topics such as mental health across all policies, promotion and prevention, or equal access for all. The support to mental health at international level as a line of action under the EU Global Health Strategy figured also prominently in the discussions.



A call for [best and promising practices on mental health](#) was launched on the European Commission's Best Practice Portal in July 2023. This call supports the implementation of actions identified in the Commission Communication on a comprehensive approach to mental health. The 20 flagship actions of the Communication are being implemented via policy actions, projects and collaborative work between the

Member States in the mental health subgroup of the Public Health Expert Group as well as with stakeholders. Close collaboration with other services is also continuing to implement actions falling under their responsibility areas. The proposed measures will also benefit from structured financial support under the Healthier Together initiative.

EU funding for health. The EU4Health Programme is the main financial instrument to support the Union's health initiatives, both legislative and non-legislative. Supported by the European Health and Digital Executive Agency (HaDEA), DG SANTE has monitored the implementation of the [EU4Health annual work programmes](#) 2021, 2022 and 2023. The third annual work programme for 2023 was adopted by the Commission on 21 November 2022 with a budget of EUR 735.8 million. Work on the mid-term evaluation of the programme started and a call for evidence was published on 5 December. In parallel DG SANTE developed a sound performance and evaluation framework in view of monitoring the EU4Health Programme's performance and to deliver its midterm review by the end of 2024. The Commission has signed the association agreement to the EU4Health Programme with Moldova in February 2023. It also completed the negotiations with Montenegro and has signed the association agreement on 19 January 2024.

Based on DG SANTE's checks and verifications, in accordance with the relevant corporate criteria, all performance information is considered reliable.

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. DG SANTE led on the implementation of the [Europe's Beating Cancer Plan](#) launched in 2021 to address cancer prevention, treatment and care. Ahead of World Cancer Day on 4 February, the Commission and the Organisation for Economic Co-operation and Development (OECD) published [the first Country Cancer Profiles](#) for all EU Member States, Norway and Iceland, as part of its Cancer Inequalities Register. Also, on 23 January, the Commission launched the [European Cancer Imaging Initiative](#) to

support healthcare providers, research institutes and innovators in making the best use of innovative data-driven solutions for cancer treatment and care.

May marked the annual European Week Against Cancer, featuring activities connected to awareness raising about cancer prevention, access to treatment and support for patients and people with a history of cancer. Communication activities included the publication of a dedicated [webpage on EU4Health funded projects](#) with factsheets and videos highlighting their links with the Cancer Plan, as well as a stakeholder webinar. The week also saw the launch of #GetScreenedEU, a campaign on cancer screening, that sought to raise awareness of the need for and benefits of cancer screening, and of the EU Cancer Plan in general. The campaign targeted adults aged 40-60 from disadvantaged backgrounds, in a wide range of

countries, and ran throughout the year. In the same month, the [EU-US Health Task Force was launched](#) with the aim to enhance cooperation notably in the area of cancer. The Task Force established two expert-level working groups focused on childhood/young adult cancer and lung cancer in the context of Europe's Beating Cancer Plan and the US Cancer Moonshot. This collaboration aims to facilitate peer-learning, exchange best practices, and advise on the development of possible joint initiatives to improve cancer outcomes across the globe.

Since 2021, the Commission launched 36 projects to implement the beating cancer plan, 12 of those in 2023.

DG SANTE prepared a Commission proposal for a Council Recommendation on vaccine-preventable cancer to support Member States in boosting the uptake of vaccination against Human Papillomaviruses and Hepatitis B virus in all affected population groups. DG SANTE also started work to prepare a Commission Recommendation for reducing human health risk associated with the use of sunbeds, which is planned to be adopted by the end of March 2024.

In addition, DG SANTE is jointly working with DG FISMA to facilitate the development of a Code of Conduct on Fair Access of Cancer Survivors to Financial Services to be agreed by stakeholders in 2024. DG RTD is leading the Horizon Europe Cancer Mission and together with DG SANTE ensures synergies with the Cancer Plan. In order to bring cancer actions closer to the citizens, the Network of National Cancer Mission Hubs project, ECHoS was launched in May 2023, involving 28 countries and 57 partners. They are operating at national, regional and local levels. An important milestone of the Cancer Plan flagship action UNCAN.eu - Understanding Cancer research data platform was reached in November 2023 when the 4.UNCAN.eu project delivered a blueprint proposing the setup of a European Federated Cancer Research data hub and a series of use cases, addressing major challenges in cancer research. To ease the life of cancer patients, a study was carried out about the European Cancer Patient Digital Center, a federated digital platform that will empower patients to access, control and share their own health data, as well as to find information and support. As part of its citizen engagement activities, the EU Cancer Mission launched a dialogue with young cancer survivors, engaging them in four workshops throughout 2023 and a conference on 7 February 2023 to discuss on how to improve their quality of life. These interactions have contributed to shape two topics related to childhood cancer and survivorship, which were included under the EU4Health Work Plan 2024 and the Mission Work Programme 2024.

Financed through the EU4Health work programme, DG SANTE continued to prepare for the establishment by the end of 2025 of an EU Network of Comprehensive Cancer Centres that will enable countries to work together to treat patients with complex conditions. A training programme to support a high-quality workforce, crucial for high quality care, is also being funded by that programme. This will also support the implementation by Member States of the [Council Recommendation on cancer screening](#), adopted in December 2022 by the Council.

Tobacco control. Tobacco use is one of the main causes of cancer and the single largest avoidable health risk in the EU (27% of all cancers are attributed to its use). DG SANTE has

long engaged in efforts in the EU and globally to reduce tobacco consumption. In the context of its evaluation, in February 2023 DG SANTE launched [a public consultation on the tobacco control legislation](#) – the Tobacco Products Directive and the Tobacco Advertising Directive – in line with the ambition of creating a ‘Tobacco-Free Generation’, where less than 5% of the population uses tobacco by 2040, as set out in Europe’s Beating Cancer Plan. In parallel, DG SANTE continued to work on a proposal for revising the 2009 Council Recommendation on smoke-free environments.

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

Pharmaceutical Strategy for Europe. DG SANTE continued to work on the actions under the [Pharmaceutical Strategy for Europe](#) that was launched in 2020 to create a future-proof and crisis-resistant framework ensuring Europe’s supply of safe and affordable medicines. A flagship initiative for the implementation of the Strategy is the revision of the general EU pharmaceutical legislation and the EU legislation on medicines for children and rare diseases. Commission proposals for a new Regulation and a new Directive were adopted on 26 April 2023. These two proposals were accompanied by a Communication on the pharmaceutical reform and on measures addressing antimicrobial resistance (AMR), and by a Commission proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (AMR) (see below 2.3).



The proposed [revision of the pharmaceutical legislation](#) aims to set up a future proof legislative framework that fosters innovation including in areas of unmet medical need (including antimicrobials); to improve access to high quality, safe, efficacious and affordable medicines in the EU; to enhance security of supply ; and to reduce regulatory burden. Drawing lessons from the COVID-19 pandemic, the proposed revision will support a crisis-resistant pharmaceuticals system. It focuses on innovation works in coherence with the proposal for a European Health Data Space and with the ongoing revision of the supplementary protection certificate for medicinal products to create a competitive environment for innovation and investment in the EU. The revision also addresses a number of specific shortcomings that were detected during the evaluations on the [legislation on medicines for children and rare diseases](#), so as to increase the development of these products in particular in areas of unmet medical needs.

The Pharmaceutical Package was successfully promoted, with extensive media coverage and a successful campaign with digital ads in online news-sites, to raise awareness of the Commission’s proposals. From May to November 2023, an 11-part series on Euronews’ [Smart Health: EU Health Union](#), explored the problems being addressed by the revision of the EU’s pharmaceutical legislation and the Commission’s proposed solutions.

The continued availability of safe, effective and affordable medicines for Europeans is a top priority for the Commission. On 24 October the College adopted a [Communication to address medicine shortages in the EU](#). Flagship actions proposed by the Communication include the creation of a Voluntary Solidarity Mechanism for Member States facing critical shortages (put in place in October 2023), a pan-European list of critical medicines and a [Critical Medicines Alliance](#). On 12 December, the Commission published the [first Union Critical Medicines list to tackle shortages](#), together with the European Medicines Agency (EMA) and the Member States' Heads of Medicines Agencies (HMA). It is an important part of the EU's efforts under the European Health Union to ensure patients have the medicines they need, by fostering the security of supply of critical medicines and preventing shortages from occurring. It is also part of the EU's efforts to improve its resilience and strategic autonomy in the face of geopolitical and unexpected challenges. As to the Alliance, it will explore how to diversify global supply chains through strategic partnerships and how to boost Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients in a coordinated way, develop a common strategic approach to medicines stockpiling in the EU and help leverage and align EU and national funding.

DG SANTE has continued in 2023 to develop the **affordability agenda** of the Pharmaceutical strategy for Europe notably in the NCAPR group (national competent authorities for pricing and reimbursement and public health care payers) to improve the affordability and cost-effectiveness of medicines and health system's sustainability, in the area of public procurement with the purpose of fostering competition and improving access. A study was drafted and discussed in the NCAPR group assessing procurement procedures and how to factor in the latter considerations related to 'green production' and security and continuity of supply.

In addition, one of the measures announced in the pharmaceutical strategy for Europe is the revision of the rules on variations (changes to the terms of a marketing authorisation) to make 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. The work on the revision is ongoing and following the opening of a feedback period on the Call for evidence at the end of summer 2023, the legislative act was submitted for public consultation in February 2024.

Implementation and application of the pharmaceutical legislation. Of the 68 new medicines authorised for human use in 2023, 37 included a new active substance, and 13 were authorised for treatment of rare diseases (of which 1 is an advanced therapy medicine). During the course of 2023, the Commission adopted 1159 decisions amending marketing authorisations (931 for medicinal products for human use, 228 for medicinal products for veterinary use) and 137 new designations for orphan medicines. As to the result indicator '2.2.A: Access to centrally authorised medicines for unmet needs', 19 new authorisations were granted (see Annex 2).

As of 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS) in line with the Clinical Trials Regulation (536/2014) which became effective one year earlier (31 January 2022). CTIS is

now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data.

On 25 September [a political agreement was reached](#) between the European Parliament and the Council of the EU on the Regulation on fees charged by the European Medicines Agency (EMA). The new rules, proposed by the Commission in December 2022, will ensure that these fees better reflect EMA's work to assess the quality, safety and efficacy of medicines before they are authorised in the EU, allowing the Agency to continue delivering scientific excellence in the evaluation and supervision of human and veterinary medicines. The fees will also better cover the important scientific contribution of the Member States' authorities to this process. The new Regulation was adopted in January 2024.

International cooperation in the area of pharmaceuticals. On 30 May 2023, a milestone was reached in implementation of the **EU-US Mutual Recognition Agreement** on inspections in the field of veterinary medicines. The EU [recognised](#) the US FDA as equivalent authority for veterinary products. At the same time, the US Food and Drug Administration (FDA) confirmed that sixteen (16) national competent authorities have pharmaceutical Good Manufacturing Practices (GMP) inspection capability, capacity and procedures for veterinary products, equivalent to those of the US. FDA is working on completing the recognition of the remaining national competent authorities.

To implement this important aspect of the EU Global Health Strategy, 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 line with the EU pharmaceutical strategy, while promoting the EU regulatory system and making the EU voice heard.

Health Technology Assessment (HTA). Health Technology Assessment is an evidence-based process that independently and objectively assesses a new or existing technology and compares it with other health technologies. It is an essential tool in the formulation of effective and innovative health policies. The [new HTA Regulation](#) that established a legal framework for cooperation of Member States on the clinical assessment of medicinal products and medical devices at Union level entered into force in January 2022. In preparation for its entry into application in January 2025, the work in 2023 focused on establishing the full governance structure of the new EU HTA system, including the establishment of all four subgroups of the Member State Coordination group with elected chairs and co-chairs (Joint Clinical Assessment, Joint Scientific Consultations, Methodologies and Emerging health technologies). A stakeholders' network was established as stipulated under the Regulation and met twice in 2023. The first release of the dedicated secure IT Platform went live on 4 October 2023 with all members of the coordination group and subgroups on-boarded. The IT Platform will be the central location for all the joint work. DG SANTE started work on the implementing act on the procedures for joint clinical assessment of medicinal products and on the implementing act on preventing conflict of interest.

DG SANTE organised three regional information days to raise awareness on the Regulation on Health Technology Assessment in Stockholm, in Athens and in Seville. The service contract

with the Consortium EUnetHTA 21 closed in September 2023 and a new tender was launched on HTA capacity building under EU4Health Programme in December 2023.



Medical Devices and In Vitro Diagnostic Medical Devices

Medical devices and *in vitro* diagnostic medical devices (IVDs) play a fundamental role in saving lives through innovative healthcare solutions. DG SANTE continues to work intensively to support the implementation of the [Medical Devices Regulation](#) (MDR) and [In Vitro](#)

[Diagnostics Medical Devices Regulation](#) (IVDR) in light of persisting challenges. On 6 January 2023, the Commission adopted a proposal to give more time to certify medical devices to mitigate the risk of shortages. This contributed to address the significant challenges remaining in ensuring sufficient capacity of notified bodies and readiness of manufacturers in order to allow medical devices and in vitro diagnostic medical devices to be certified under the new Regulations. The Commission proposal was [adopted by the Council on 7 March](#).

6 new notified bodies assessing the conformity of devices have been designated for medical devices and 3 for *in vitro* diagnostics in 2023, bringing the total numbers to 43 and 12 respectively. The Commission has adopted 1 proposal for amending the MDR and IVDR, 8 new implementing and 3 new delegated acts, a Staff Working Document and a Commission guidance in 2023 and 18 new technical guidance documents have been endorsed by the Medical Device Coordination Group to provide guidance on the implementation of the Regulations, which brings the total number of guidance documents endorsed by the Group to 121. To provide additional targeted support 10 actions co-funded by the EU4Health Programme have also been put in place and 5 European Reference Laboratories were designated.

The European Union assumed in 2023 the role of Chair and Secretariat of the International Medical Device Regulators Forum (IMDRF). IMDRF promotes inter alia the EU regulatory framework, international collaboration between regulators, and aims at regulatory convergence and to ensure patient safety. Under the EU leadership, among other, the role of the Forum was strengthened with enlargement of membership and inclusion of more regulators, the governance structure was improved, the first training to facilitate reporting of unexpected incidents was published, new expert groups were launched.

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

On 5 May 2023, the World Health Organisation (WHO) officially announced the end of COVID-19 as a global health emergency. Commission President Ursula von der Leyen [said](#) that the EU was now far better prepared to face future health crises, with new tools to react quickly to emerging health crises. She also recalled the determined action taken by the EU at global, EU and Member State level, and the resilience and solidarity of our citizens in overcoming

the pandemic and its consequences. The [2023 State of Health Preparedness Report](#), drafted by SANTE, reflects and summarizes key actions for better preparedness and response.

DG SANTE entered 2023 with a strengthened mission in this area, thanks to [the new Regulation on serious cross-border health threats](#) that entered into force in December 2022. This Regulation updates the EU legislation and modus operandi in the vital areas of prevention, preparedness, surveillance, risk assessment, early warning, and response. It does so by building on the lessons learned during COVID-19 and provides a robust legal framework with which to meet future threats to public health, whether they be of biological, chemical, environmental or unknown origin. Through its international dimension, the Regulation makes an important contribution to the EU Global Health Strategy's priority to prevent and combat health threats. The first reporting on the state of preparedness from the side of Member States, based on this new Regulation, was completed in December 2023 and will be followed by country assessments in 2024.

As a key milestone in the EU Global Health Strategy's goal to foster digitalisation as a fundamental enabler, on 5 June 2023, the Commission and the World Health Organization (WHO) announced the launch of a landmark [digital health partnership](#), whereby the WHO will take up the EU system of digital COVID-19 certification (EU DCC). This will establish a global system that will help facilitate global mobility and protect citizens across the world from on-going and future health threats. This is the first building block of the WHO Global Digital Health Certification Network (GDHCN).

It is based upon the solid foundations of the EU DCC framework, principles and open technologies. Through this collaboration, WHO will facilitate the process globally under its own structure with the aim to allow the world to benefit from the convergence of digital certificates. This partnership will include close collaboration in the development, management and implementation of the WHO system, benefitting from the ample technical expertise of the European Commission, and of DG SANTE in particular.

Preparedness and Response. The regulation reinforcing EMA's role in crisis preparedness and management of medicinal products and medical devices puts some of the structures and processes established during the COVID-19 pandemic on a permanent footing. EMA is now responsible for monitoring medicine shortages, as well as reporting shortages of critical medicines during a crisis.

The [Joint Procurement Agreement for medical countermeasures](#) has been 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 Q2/2024.



Vaccination. In 2023 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. In addition to the 7 COVID vaccines already authorised, the Commission authorised the HIPRA COVID vaccine (Bimervax) in March; two

adapted COVID-19 vaccines (Comirnaty XBB.1.5 and Spikevax XBB.1.5) in September targeting the new SARS-CoV-2 Omicron strain, and the first protein-based adapted COVID-19 vaccine targeting the Omicron strain (Nuvaxovid XBB.1.5) in October. In 2023, DG SANTE finalised the implementation of actions called for in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases from 2018. Building on the lessons learned from the COVID-19 pandemic and in line with the Commissioner's Mission Letter, DG SANTE also continued its communication campaign to raise awareness of the benefits of vaccination throughout the life course in 2023. Under the [United In Protection](#), editable material and toolkits were provided to multipliers on four key strands: COVID-19, seasonal influenza, HPV and measles. This was accompanied by an EU4Health financed initiative to address misinformation including support to the European Vaccination Information Portal, the publication of a comic book series for teens and an online teacher training course. DG SANTE also actively participated in corporate initiatives to address mis- and disinformation, notably through the Network Against Disinformation and weekly contributions to the Fighting the Fallacies newsletter.

Antimicrobial Resistance (AMR).

With more than 35,000 deaths in the EU every year due to antibiotic-resistant infections, equivalent to the yearly numbers of deaths from influenza, tuberculosis and HIV/AIDS combined, the problem of AMR is worsening. DG SANTE continued supporting Member States to address



this challenge and, as a key element of the EU Global Health Strategy, has taken forward work with international partners to advocate for its inclusion in the Pandemic Agreement. Specifically, DG SANTE promoted the “One Health” approach within multilateral fora at the UN, WHO, WOA, FAO, UNEP, Codex, G7 and G20 level, and continued the strong cooperation with the U.S., Canada, Norway and UK at the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR). DG SANTE hosted the 2023 session of the TATFAR meeting in Luxembourg in November. DG SANTE carried out a One Health AMR joint country visit with the ECDC in a potential candidate country and five audits in Member States (one on rabies and four on avian influenza).

DG SANTE pursued the implementation of the 2017 AMR Action Plan laying out over 70 actions to fight AMR. Following on from a [report reviewing Member States' One Health National Action Plans \(NAPs\)](#) published in November 2022, on 13 June 2023 the [Council adopted the Commission's proposal](#) for a Recommendation to strengthen EU action against AMR. The Recommendation focusses on strengthening national One Health actions plans on AMR and on infection prevention and control and reinforced surveillance and monitoring of AMR and antimicrobial consumption. It also aims at fostering research, innovation and access to antimicrobials and other medical countermeasures, and at strengthening antimicrobial stewardship and prudent use through the education and training of professionals. It sets several EU targets, developed with the European Centre for Disease Prevention and Control, for 2030, in particular: a 20% reduction of the total consumption of

antibiotics in humans; at least 65% of the total consumption of antibiotics in humans should be effective (use of the right antibiotic); and, a reduction of infections of three key antibiotic-resistant bacteria, which will apply mainly to hospitals. These recommended targets for the EU, which are also translated for each national level, will help the EU to tackle AMR taking into account national specificities without compromising patients' health and safety. They will also allow better monitoring of infections and consumption of antibiotics in the coming years so as to adjust policy making accordingly.

This Recommendation also confirmed the EU's international leadership on AMR and called on the Commission and the Member States to cover AMR in the pandemic agreement currently under negotiation. It also invited the Commission to keep AMR high on the agenda of the G7 and G20 and work in collaboration with international organisation, in particular the Quadripartite (FAO, UNEP, WHO and WOA).

In addition to the usual press and social media promotion, DG SANTE communicated on the threat of AMR throughout 2023 and explored the topic and the Commission's policy response in an episode of the [Euronews series, Smart Health: EU Health Union](#).

To address increasing AMR, it is essential to ensure both access to existing antimicrobials and the development of novel effective ones. The revision of the EU pharmaceutical legislation proposes therefore a temporary mechanism of transferable data exclusivity vouchers (TEVs), for the development of novel antimicrobials to be granted and used under strict conditions. Measures are also proposed ensuring their prudent use and lowering their impact on the environment.

[Under the EU4Health programme](#), €50 million have been set aside for a new joint action on AMR. The new joint action, to start early next year, should bring together the authorities of all EU Member States, Norway, Iceland, and Ukraine to support them to implement diverse policies and measures to tackle AMR across the One Health approach. Another €22 million have been set aside through the Health Emergency Preparedness and Response Authority ([HERA](#)) to establish a coordination network which will prepare the implementation of bringing AMR medical counter measures to the market, as well as for procurement.

DG SANTE continued to work closely with global allies including the U.S., Canada, Norway and the UK under TATFAR, with the Commission hosting an in-person TATFAR meeting in Luxembourg in November 2023.

DG SANTE continued to support AMR advocacy on following the One Health approach through the second phase of BTSF training programme for non- EU countries on AMR.

Other engagement at international level. DG SANTE made an important contribution to the implementation of the new [EU Global Health Strategy](#), with the wide panoply of actions referenced in the different sections of this document.

Beyond these actions, DG SANTE participated fully in the work and multilateral processes related to international public health, including in the context of the United Nations, the World Health Organization, G7 and G20, and OECD to ensure coordinated global action.

DG SANTE continued its leading role in the intergovernmental negotiations at the WHO on an international agreement on pandemic prevention, preparedness and response (PPR), as well as in the revision of the International Health Regulations.

DG SANTE contributed to galvanise G7 and G20 support for important global health work, for instance to foster digital health, improve financing of health system and pandemic response or promote equitable access and delivery of pandemic countermeasures. It also actively promoted the Pandemic Fund so that it could provide dedicated long-term financing to address gaps in PPR capabilities in low-income countries, helping mobilise more than USD 2 billion in its first call for proposals. DG SANTE played a leading role in the negotiations at the United Nations of the outcomes from the three UNGA High Level meetings on PPR, universal health coverage and tuberculosis. It also continued to champion the importance of universal health coverage, including for the achievement of the health-related targets of the UN 2030 Sustainable Development Agenda, and of the implementation of the One Health approach to tackle inter alia the impacts of the triple planetary crisis and antimicrobial resistance.

DG SANTE also deepened its partnership and dialogue with civil society stakeholders and hosted the annual high-level meeting of the Global Health Policy Forum, a key element of the implementation of the EU Global Health Strategy. It continued to ensure good Commission coordination and input to WHO governing bodies' meetings and took forward its technical cooperation with the WHO. Another example was collaboration with the WHO in the work to develop an interim medical countermeasures platform to better face future pandemics.

DG SANTE also ensured the Commission's endorsement, on behalf of the EU, of the 28th UN Climate Change Conference (COP28) first ever Declaration on "climate and health", which acknowledges the growing health impacts of climate change on communities and countries. This follows the EU Global Health Strategy's priority to tackle this key determinant of health.

When it comes to bilateral relations, the launch of the EU-US Health Task Force in May 2023 led to enhanced cooperation with the United States on cancer and strengthening the global health architecture. The EU-US Health Task Force, with three strands on cancer, global health threats, and the global health architecture has been launched on 17 May 2023. On cancer, the cooperation will focus on paediatric and lung cancers. Work also progressed to set up the EU-Canada Health Policy Dialogue under the Strategic Partnership Agreement, and high-level events with partners like Latin America, Japan or Korea enhanced cooperation in global health matters.

In bilateral cooperation, DG SANTE continued to actively support the enlargement process regarding the EU health *acquis communautaire*, as well as its work with the six Western Balkan Eastern Partnership countries. In June, an Arrangement for *Cooperation* on Health was signed with the Ministry of Health of Ukraine. The six areas of cooperation are: mental health, access to healthcare and catering to the health needs of refugees, the return of patients to Ukraine and strengthening its rehabilitation system, enhancing the work of Ukraine on rare diseases and continued funding through the EU4Health programme.

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

In 2022 DG SANTE continued to support Member States in improving the effectiveness, accessibility and resilience of their health systems. This work is key to support the Member States in achieving the UN Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages) and to improve national health systems' resilience in the wake of the COVID-19 crisis.

Digital Health. In May 2022 [the proposal for a Regulation on the European Health Data Space](#) was adopted, together with a [Commission Communication](#) to the EP and Council. The goal of the proposed regulation is to empower citizens to control the use of their health data in their home country as well as in other Member States. The initiative, which is one of the central building blocks of the European Health Union, will also offer a consistent, trustworthy and efficient framework to use health data for research, innovation, policy-making and regulatory activities, while ensuring full compliance with the EU's high data protection standards. The legislative process has advanced in the European Parliament and the Council towards timely adoption of the regulation.

In parallel, exploratory and preparatory activities for the implementation of the European Health Data Space have been initiated. In the area of primary use of health data, the expansion of the MyHealth@EU infrastructure for the cross-border exchange of patients' health data continued with the support from EU funding, including EU4Health. Over 20 new direct grants to Member States with over EUR 30 million of EU contribution, were signed to support the rollout and expansion of this infrastructure at Member State level. DG SANTE collaborated with the Member States in the eHealth Network (eHN) on interoperability guidelines for Hospital Discharge Reports and Medical Imaging. A new Joint Action was launched at the end of 2023 to support the EHDS technical specifications, including for use in electronic health record (EHR) systems. Furthermore, the Commission assisted Member States in the adoption and implementation of SNOMED CT, international clinical terminology system. It signed a contribution agreement with the WHO which among others aims to improve the readiness of the Member States and other countries for the adoption of ICD-11, a system for international classification of diseases developed by WHO.

In the area of secondary use of health data, DG SANTE is supporting the implementation of the pilot project of the HealthData@EU infrastructure. This infrastructure aims to facilitate cross-border information exchange among Health Data Access Bodies, Data Users, and Data Holders. The ongoing pilot builds upon the solutions proposed by the Joint Action TEHDAS which was successfully completed in 2023. DG SANTE has supported the Member States in the establishment of Health Data Access Bodies at the national level. It also launched a pilot of the central interoperability platform crucial for the operation of the HealthData@EU infrastructure. A new Joint Action will prepare the ground for EHDS technical specifications for secondary use of health data. Additionally, a capacity-building initiative is underway to support the Community of Practice of Member States' Health Data Access Bodies.

As noted above, from 1 July 2023 the WHO took up the EU technical system of digital COVID-19 certification (EU DCC) as the first building block of the WHO Global Digital Health Certification Network (GDHCN).

Health systems. DG SANTE has continued to work in collaboration with SG-RECOVER and ECFIN to assess health-related investments and reforms proposed in the Recovery and Resilience Plans and monitor their implementation. All 27 national plans adopted include measures related to health. In addition, DG SANTE contributed to the 2023 European Semester, including through the delivery of the thematic Annex on 'Health and Health Systems' in all 27 [Country Reports](#). Furthermore, [Country Specific Recommendations](#) addressing healthcare challenges were issued for 6 Member States. DG SANTE has continued to generate country-specific and cross-country knowledge on health systems as part of the "State of Health in the EU" cycle financed under the EU4Health Programme, a project carried out in collaboration with the OECD and the European Observatory on Health Systems and Policies. In December 2023, SANTE organised a webinar, with over 600 participants, during which the 2023 edition of [Country Health Profiles](#) was launched, together with a [Synthesis Report](#) (Staff Working Document). The Synthesis Report focused on three key messages – the importance of addressing mental health, vigilance to increasing health inequalities, and the need to focus on investments in health and good health data for policy-making. Moreover, the EU Expert Group on Health Systems Performance Assessment published its report on '[Mapping metrics of health promotion and disease prevention for health system performance assessment](#)' and held a webinar on the topic in June 2023. Press and social media materials were prepared at the launch of the report and received good coverage. The Expert Group, with its revamped mandate, also agreed on 5 priority topics for its future work plan: health workforce, mental health, environmental impact of health systems, health inequalities and governance of health systems performance assessment. Finally, DG SANTE continued working with the OECD and the European Observatory on Health Systems and Policies on a methodology for Member States to test the resilience of their health systems. This methodology will be published in early 2024 in the form of a handbook and will be made available to Member States to conduct resilience tests to improve preparedness for different shocks to health systems (e.g. pandemics, climate change, AMR).

The 24 European Reference Networks (ERNs) for rare and complex diseases (ERNs), set up under the [Cross-Border Healthcare Directive](#), bring together more than 1600 highly specialised healthcare providers to improve access to diagnosis and treatment for patients in Europe. A EUR 77 million call for direct grants was launched in October and work continued on the upcoming Joint Action JARDIN worth over EUR 18 million which is intended to increase the sustainability of the ERNs and ensure their integration into the national healthcare systems. DG SANTE appointed an Independent Body to conduct an evaluation of the first five years of operation of the 24 networks and 836 of their members. The results show that the ERNs system is suitable for its purpose and is delivering results for patients with rare diseases and their families. All 24 networks got satisfactory results, as well as 88% of their evaluated members, while 8% need to implement an improvement plan and 4% have been terminated. The results of the evaluation will be used for the next phase of development of the Networks.

Substances of human origin (SoHO). DG SANTE worked throughout 2023 towards reaching the conclusion of the legislative process for the adoption of the [proposal](#) (issued in July 2022) to revise the EU legislation on the safety and quality of substances of human origin. On 14 December 2023 a political agreement was reached between the European

Parliament and the Council of the EU on the **Regulation on blood, tissues and cells**. The revision reinforces the safety both of patients treated with blood, tissues and cells therapies and of the donors. It strengthens the quality and continuity of supply of the substances used and increases the oversight by national public authorities, it supports innovation and facilitates the development of new therapies. The new Regulation will be adopted in 2024.

Health Workforce. Adequate staffing levels have become a very urgent issue during the COVID-19 pandemic, which exacerbated pre-existing shortages and added to existing structural challenges in health care delivery. The Commission put in place several actions to support Member States in addressing staff shortages and skills mismatches. The [Joint action HEROES on health workforce planning and forecasting](#) kicked-off in the first quarter of 2023. Projects addressing shortages of health professionals in medical deserts, retention of staff and task-shifting reached their maturity in 2023 and the work will conclude in 2024. The Pact for Skills large-scale partnership of the health workforce, launched on 13 December 2022, continued its work on developing a Skills Strategy for health workforce (which will be put to public consultation in 2024) and on innovative curricula with the focus on digital and green skills. In spring 2023, seven cross-European projects were launched, with funding from EU4Health, addressing continuous professional development for health professionals, with a focus on digital skills. The projects cover several areas: oncology, AMR, gynaecology, hospital care and more transversal and advanced digital skills in healthcare.

Patients' right to cross-border healthcare. EU citizens have the right to access and be reimbursed healthcare in any EU country. DG SANTE continued during 2023 to undertake compliance checks and bilateral structural dialogues with the Member States in regard to the provisions of Directive 2011/24/EU on Cross-border Healthcare.

2. INTERNAL CONTROL AND FINANCIAL MANAGEMENT

Assurance is provided on the basis of information on the efficiency and effectiveness of internal control systems and governance processes. The management monitors the functioning of the internal control systems on a continuous basis and carries out an objective examination with internal and external auditors. The results are explicitly documented and reported to the Director-General. The following reports / documentation have been considered:

- Annual reports on budget implementation drafted by the Authorising Officers by Sub-delegation, including their hand-over reports;
- Reports of the central financial cell on the recorded exceptions/non-compliance events or “confirmation of instructions” according to Article 92(3) of the Financial Regulation;
- Report of the Public Procurement Committee ("Comité des Marchés Publics") on ex-ante controls of public procurement procedures;
- Audit reports and the annual overview report of DG SANTE’s on-the spot controls;
- Report of the Director in charge of Risk Management and Internal Control (RMIC) on the annual assessment of the internal control principles;
- Limited conclusion of the Internal Auditor on the state of internal control, and the observations and recommendations reported by the Internal Audit Service (IAS);
- The observations and the recommendations reported by the European Court of Auditors (ECA);
- Reports on control results from the Health and Digital Executive Agency (HaDEA);
- Reports on control results from EU decentralised agencies to which DG SANTE is partner.

The systematic analysis of the available evidence provides sufficient guarantees as to the completeness and reliability of the information reported and results in the full coverage of the budget delegated to the Director-General of DG SANTE.

This section covers the control results and other relevant elements that support management's assurance. It is structured into 2.1. Control results, 2.2. Audit observations and recommendations, 2.3. Effectiveness of internal control systems and resulting in 2.4. Conclusions on the assurance.

2.1 Control results

This section reports on the control results used by management to support the assurance on the achievement of the internal control objectives (ICO) ⁽²⁾. DG SANTE's assurance building and materiality criteria are outlined in annual activity report annex 5. The annual activity report 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.

In line with the 2018 Financial Regulation (FR), DG SANTE's assessment for the new reporting requirement is as follows: DG SANTE has no cases of "confirmation of instructions" (FR article 92.3), "financing not linked to costs" (FR article 125.3), "Financial Framework Partnerships >4 years" (FR art 130.4) or "flat-rates >7% for indirect costs" (FR article 181.6). DG SANTE has one case to report of "derogations from the principle of non-retroactivity" pursuant to FR article 193, since all grants related to veterinary and plant emergency measures derogate from FR article 193.2 as set out in the Single Market Programme Regulation ⁽³⁾, article 3.5.

The objectives, indicators and assessments in this section cover all expenditure and other significant non-expenditure items ⁽⁴⁾. DG SANTE managed financial operations under two policy areas, Health and Food Safety. 2023 was the third year of implementing the new Multi-annual Financial Framework (MFF) covering the 7-year period from 2021 to 2027 ⁽⁵⁾.

About 37% of the 2023 budget implemented by DG SANTE fell under direct management, mainly through grant agreements and public procurement; DG SANTE implemented the remaining 63% under indirect management of which 5% for contribution agreements, mainly with international organisations such as the World Health Organisation (WHO) and the Organisation for Economic cooperation and Development (OECD) and 95% for subsidy payments to four EU decentralised agencies for implementing their tasks.

The assurance building processes rely, first and foremost, on error rates 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.

⁽²⁾ 1) Effectiveness, efficiency and economy of operations; 2) reliability of reporting; 3) safeguarding of assets and information; 4) prevention, detection, correction and follow-up of fraud and irregularities; and 5) adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments (FR Art 36.2). The 2nd and/or 3rd Internal Control Objective(s) (ICO) only when applicable, given the DG's activities.

⁽³⁾ Regulation (EU) 2021/690 of 28 April 2021 on the Single Market Programme (SMP)

⁽⁴⁾ These include only the significant amounts, i.e. assets (intangible assets exceeding EUR 5 million); no other items were significant, for example, revenue operations did not account for more than 5% of the total budget allocation in 2022.

⁽⁵⁾ Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020.

Figure 2.1 DG SANTE's 2023 budget implementation in comparison to 2022
(Payments made in 2023: EUR 589 million (2022: EUR 467 million))

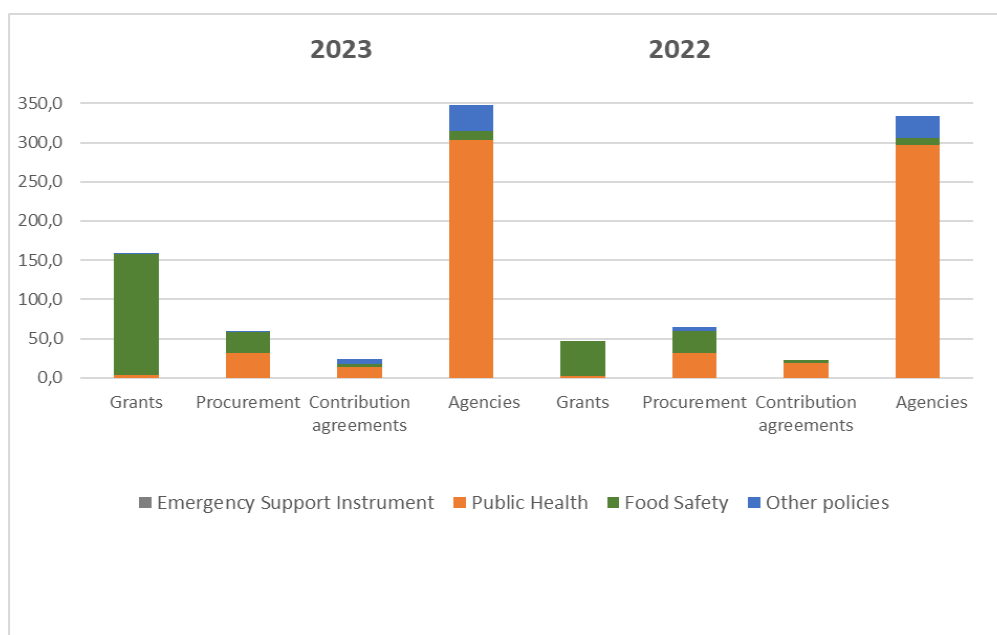


Table 2.1 Overview table of DG SANTE's budget implementation - payments made in 2023

Management mode	Direct management			Indirect management		Total	
Risk type / Activities	Grants	Procurements	Budget transfer to HaDEA	Contribution agreements	Subsidy payments to agencies		
	M€	M€		M€	M€	M€	%
Public Health	2,8	31,0	219,9	14,3		268,0	28,3%
Food Safety	154,5	24,0	137,0	3,4		318,9	33,7%
Emergency Support Instrument						-	0,0%
Administrative expenditure, mostly for office building in Ireland		3,1				3,1	0,3%
Other policies*	0,4	1,4		6,4	33,6	41,7	4,4%
HaDEA					16,8	16,8	1,8%
ECDC					90,2	90,2	9,5%
EFSA					147,4	147,4	15,6%
EMA					50,1	50,1	5,3%
ECHA-biocides					9,7	9,7	1,0%
Total (including HaDEA)	157,7	59,5	356,9	24,1	347,8	946,0	100%
Total (excluding HaDEA as in Annex 3)	157,7	59,5		24,1	347,8	589,0	
EC balance sheet category							M€
<i>Intangible Assets - internally generated IT software</i>							22,1
<i>Inventories of antigen stocks for animal diseases</i>							9,6

ad *: Co-delegations received from other DGs, incl M€33,6 of administrative credits for HaDEA

EU4Health Programme – 2023 work programme

- Under the general objective 2 “Promoting our European way of life”, the EU4Health Programme⁶ 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 currently has an envelope of EUR 5.3 billion (2021-2027). On 1 February 2024, the European Council decided to cut the EU4Health budget by EUR 1 billion to finance the support to Ukraine. This cut represents a 20% reduction of the total programme budget or 33% of the remaining budget for 2024 to 2027.
- DG SANTE’s spending in the Health policy area remained relatively stable over the last three years. In 2023, DG SANTE managed a budget of EUR 268 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. About 80% of the payment budget for the Health Programme in 2023 was implemented by HaDEA. DG SANTE implemented the remaining 20% mainly through contribution agreements with international organisations under indirect management (see Annex 11) and public procurement procedures, in particular for IT services, such as IT systems of the European Reference Networks (ERNs), European database on medical devices (EUDAMED), MyHealth@EU services and European Health Data Space (EHDS).
- The total of payment credits was consumed to 99%. The relevant internal control systems and results are described in Annexes 6 and 7.1.

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 Programme (SMP)-Food chain strand⁷ (EUR 1.7 billion for the period 2021-2027) is allocated to specific objective 1.1 “Food and feed safety” to cover disease prevention. Smaller parts of the budget support specific objectives 1.2 “Sustainable food systems – the ‘Farm to Fork’ Strategy” and 1.3 “International promotion of EU food safety standards”.

⁶ Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme; C(2022) 317 of 14 January 2022 – 2022 work programme of EU4Health

⁷ 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

- DG SANTE's payment credits of the SMP-Food chain strand in 2023 amounted to EUR 319 million of which about 43% were implemented by HaDEA for grants pertaining to the 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 67%, of which EUR 150 million for veterinary and plant health emergency measures in the form of grants to Member States and third countries based mainly on the co-financing of eligible costs. Although the total amount of spending in the policy area Food Safety remained relatively stable over the past few years, the share of contributions to Member States' emergency measures has much increased in 2023 due to the many outbreaks of Avian Influenza and African Swine Fever in the past few years. DG SANTE also procured vaccines/antigens for the EU animal health vaccine banks and concluded a new contract for Foot and Mouth Disease virus antigens with a total value of EUR 6.4 million.
- Payment credits were consumed to 99%. The main features of the corresponding internal control systems are listed in Annex 6.1; the control results are explained in Annex 7.1.

Emergency Support Instrument⁸ (ESI) to address the COVID-19 pandemic

- The ESI expired on 31 January 2022 and was not reactivated. The last two Advance Purchase Agreements for COVID-19 vaccines were cleared in 2023: one, based on the value of vaccine doses delivered to the Member States and one after the termination of the agreement.
- In 2023, DG SANTE made no budgetary commitments nor payments. The remaining credits for budgetary commitments (EUR 26 million) and payments (EUR 29 million) stem from the 2021 top-up of EUR 750 million COVID-19 vaccines, of which DG SANTE will pay back EUR 12.3 to Member States. Funds from other sources, such as recoveries from Member States for their resales of vaccines or from a company further to the termination of its advance purchase agreement, will be delegated to other DGs to ensure that all credits will be used.

Other policy areas

- An amount of EUR 33.6 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 2023. The internal control system is described in Annex 6.2 (agencies).
- DG SANTE made a pre-financing payment of EUR 6.4 million with budget delegated from DG HOME for a contribution agreement with the International Federation of the

⁸ Emergency support under Regulation (EU) 2016/369 - In mid-April 2020, the Council activated the Emergency Support Instrument (ESI) for the period 1 February 2020 to 31 January 2022.

Red Cross and Red Crescent Societies to support mental health and psychosocial assistance for displaced people coming from Ukraine⁹.

Agencies

- DG SANTE paid subsidies to finance – partially or in full – the operating budget of HaDEA (EUR 16.8 million) and four EU decentralised agencies (EUR 297.4 million). Detailed figures and explanations are given in Annexes 6.2 and 7.1.

Building expenditure for Grange, Ireland

- About EUR 2.7 million relate to the office building in Grange, which is managed directly by DG SANTE (not by OIB or OIL).
- The payment budget was implemented to 62% in 2023, and as payments can still be made in 2024, the credits are expected to be fully used. The relevant internal control systems are described in Annexes 6.1 and 7.1 (procurement).

Balance sheet:

- DG SANTE identifies internally generated intangible assets (IT software for eHealth (EUR 7.8 million) and EUDAMED (European database for medical devices; EUR 14.3 million) of a total value of EUR 22.1 million (see section 2.1.c below).
- In its balance sheet, DG SANTE identified current assets (inventories) of a total value of EUR 9.6 million at 31 December 2023. The assets pertain to antigen stocks for Foot and Mouth Disease to carry out emergency vaccination (see section 2.1.c below). No other vaccines or antigens were in stock at the end of 2023.

2.1.1 Effectiveness of controls

(a) Legality and regularity of the transactions

DG SANTE uses internal control processes to ensure sound management of risks relating to the legality and regularity of the underlying transactions it is responsible for, taking into account the multiannual character of programmes and the nature of the payments concerned.

(1) Control objective

One of the key performance indicators 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

⁹ Together with DG SANTE's credits from the EU4Health programme, the total amount paid for this action in 2023 is EUR 8.2 million.

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 and 7.1.

Since the transfer of budget implementation tasks, including ex-post controls, to HaDEA in 2021, DG SANTE has not carried out ex-post controls anymore on the transferred grants. The last batch of previous audits in the policy area Food Safety was finalised in 2022. Therefore, 2023 is the first year for which DG SANTE does not report on an error rate of ex-post controls anymore. The grants that remain with DG SANTE are grants to Member States for their emergency measures for animal and plant health. Rather than carrying out ex-post controls for these grants, DG SANTE relies on extensive ex-ante controls, including on-the-spot financial audits with a view to correcting all detected errors in Member States' cost claims before the final payment is made.

(2) Assessment of the control results

Based on past experience and HaDEA's ex-post control results related to Member States' animal and plant health programmes, DG SANTE estimates an equivalent to the detected error of just under 2% for grants to Member States for animal and plant health emergency measures.

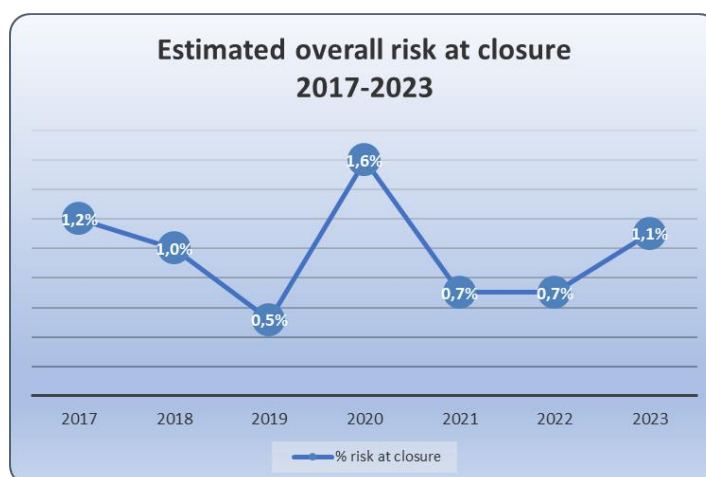
With regard to payments related to public procurement, the internal control strategy does not provide for ex-post audits in either policy area as DG SANTE concludes mostly fix-price contracts for which the error rate is estimated between 0.5% (low risk contracts based on deliveries) and 2% (for other fix-price contracts) resulting in a weighted average for 2023 of 1.4% in table 2.2 below.

The scope of DG SANTE's ex-post controls also excludes payments made under indirect management, as the error rate after ex-ante control is expected to be below 2% given that contribution agreements are signed only with international organisations that were pillar assessed. 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 1.1% for 2023.

Figure 2.2

The increase in 2023 in comparison to 2021 and 2022 is due to a large amount of clearing of past years' pre-financing payments for Advance Purchase Agreements for COVID-19 vaccines. These clearings account for a large share of procurement with a weighted average estimated error rate of 1.4%



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.

(3) Supervision of the executive agency and the decentralised agencies

For the 2023 reporting year, the executive agency HaDEA has itself reported reasonable assurance on its administrative budget as well as on the delegated budget managed by it on DG SANTE's behalf. 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 2023 of HaDEA. DG SANTE's mechanism for supervision/coordination, monitoring and reporting encompasses the work of the Steering Committee, active participation in SANTE/HaDEA Management Board meetings and day-to-day interactions at Unit level (see Annex 7.1.1.4 for more detail).

For four EU decentralised agencies (EFSA, EMA, CPVO, and ECHA for its biocides activities) for which DG SANTE was responsible in 2023, the Court of Auditors gave a positive declaration of assurance for the year 2022. With regard to ECDC, the Court issued a qualified opinion on the legality and regularity of payments underlying the 2022 accounts of ECDC due to ineligible VAT paid under HERA grants. The "emphasis of matter" in the 2022 report on EMA, the qualified opinion on ECDC's payments 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.

(4) Overview of DG SANTE's risk profile

DG SANTE's portfolio consists of segments with a relatively low error rate, ie 0% for subsidy payments to agencies; 0.5% for lump-sum grants and fix-price procurement contracts based on goods delivered, and just under 2% for other procurement contracts, resulting in a weighted average of 1.4% in table 2.2 below. An error rate of around 2% is also estimated for contribution agreements and grants to Member States for emergency measures.

This is, respectively, thanks to the inherent risk profile of the beneficiaries and funding modalities as well as the performance of the related control systems.

(5) Estimated risk at payment and at closure

Based on all the above, DG SANTE presents in the following Table 2.2 an estimation of the risk at payment and risk at closure for the expenditure managed during the reporting year:

Table 2.2: Estimated risk at payment and at closure (amounts in EUR million)

The full detailed version of the table is provided in annex 9.

DG SANTE	Payments made MEUR	Relevant expenditure MEUR	Estimated risk (error rate %) at payment		Estimated future corrections and deductions		Estimated risk (error rate %) at closure	
			MEUR	%	MEUR	%	MEUR	%
Grants to Member States in the Food Safety policy area	154,48	30,48	0,61	2,00%	0,00	0,00%	0,61	2,00%
Public procurement and other grants	62,68	831,01	11,75	1,41%	0,00	0,00%	11,75	1,41%
Contribution agreements with international organisations	23,35	0,42	0,01	2,00%	0,00	0,00%	0,01	2,00%
Contribution agreements with EU decentralised agencies	0,75	1,50	0,03	2,00%	0,00	0,00%	0,03	2,00%
Subsidies to EU decentralised agencies	297,45	261,18	-	0,00%	0,00	0,00%	-	0,00%
Total without contribution to HaDEA's operating budget	538,71	1.123,75	12,38	1,10%	0,00	-	12,38	1,10%
Health and Digital Executive Agency (HaDEA)	50,34	40,43	-	0,00%	0,00	0,00%	-	0,00%
DG SANTE total with HaDEA	589,04	1.164,17						

The estimated overall risk at payment for 2023 expenditure, 1.1%, 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. Since DG SANTE does not carry out ex-post controls (as explained in Annex 6) no further corrections to the expenditure are expected and the estimated future corrections are thus set at 0%. As a result, the estimated overall risk at closure corresponds to the estimated overall risk at payment.

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.

(6) Preventive and corrective measures

As regards the corrections carried out in 2023, DG SANTE has in place an effective mechanism for correcting errors, through ex-ante and ex-post controls, resulting in preventive and corrective measures, amounting to EUR 1.6 million and EUR 0.2 million respectively (in 2022, EUR 2.1 million and EUR 0.8 million respectively).

(b) 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 in the context of the mid-term report on internal control and the annual activity report. More than 80% of all necessary actions have been implemented. The implementation of some awareness raising actions and procedure updates had to be postponed to 2024 due to other priorities (detail is provided in Annex 71.2).

DG SANTE also contributed to the revised Commission anti-fraud strategy Action Plan adopted on 11 July 2023 (COM(2023) 405), notably to actions under section “7. Strengthen the culture of ethics and anti-fraud in the Commission”. In June 2023, DG SANTE together with OLAF organised an online interactive workshop on Fraud prevention and detection, especially addressed to DG SANTE staff. Around 180 staff members of DG SANTE participated. As in previous years, DG SANTE representatives regularly attended the Fraud Prevention and Detection Net events chaired by OLAF.

All follow-up actions to implement OLAF recommendations were closed in previous years; no new recommendation has been issued in 2023.

Based on the available information, DG SANTE has reasonable assurance that the anti-fraud measures in place are effective.

(c) Safeguarding of assets and information

In its balance sheet, DG SANTE identified internally generated intangible assets of a total value of EUR 22.1 million at 31 December 2023. The assets pertain to IT software developed by DG SANTE for eHealth (EUR 7.8 million) and EUDAMED (EUR 14.3 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. The risks linked to procurement procedures and financial circuits are covered within the previous sections.

In addition, DG SANTE identified current assets (inventories) of a total value of EUR 9.6 million at 31 December 2023. The assets pertain to antigen stocks for Foot and Mouth Disease in order to carry out emergency vaccination. No other vaccines or antigens were in stock at the end of 2023.

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. The Court of Auditors carries out annual audits on DG SANTE's accounts. In the past few years, no observation was made that would affect the intangible assets or vaccines stocks.

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.

2.1.2 Efficiency of controls

The main efficiency indicators monitored in 2023 focussed on the timeliness of budget implementation. Due to the late agreement on the new Multiannual Financial Framework (2021-2027) in December 2020¹⁰, the EU4Health Programme was adopted only on 24 March 2021 and the Single Market Programme (SMP) with the Food Safety strand in April 2021. The delay in implementation of the 2021 and 2022 budgets still had repercussions on the implementation of the 2023 budget. Thanks to timely budget transfers, DG SANTE achieved a 100% implementation of the 2023 must-use commitment credits and 99% of its expiring payment credits.

DG SANTE ensured efficient processing of payments within the legal deadlines. Supported by electronic workflows with automatic reminders of payments due, over the last few years, DG SANTE was able to increase the efficiency of its payment file handling. In 2023, DG SANTE's indicator of timely payments (99% of amounts paid on time) is the same as the Commission average of 99%. Efficiency indicators such as “time-to-inform” and “time-to-grant” (Art 194.2 of the Financial Regulation) were not applicable in 2023 to DG SANTE's grant agreements in 2023 (for more indicators and explanations see Annexes 4 and 7.2).

Timely Payments	SANTE Score	EC Score
	99%	99%

In its 2023 Management Plan, DG SANTE identified three initiatives to improve economy and realise efficiency gains. The first two initiatives aim at improving financial management through, firstly, the revision of the use of unit costs and lump-sums in the SMP – Food Chain strand, aiming at reducing administrative burden, speeding up the payment process, and reducing error rates; secondly, DG SANTE's preparations for the new SUMMA tool that will be replacing ABAC in 2025; it will combine robust security settings with the necessary flexibility

¹⁰ Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020

in the budget implementation and is expected to contain sufficient operational information to allow for clear, correct and reliable reporting.

Furthermore, DG SANTE is investing in technologies and capabilities for data cataloguing as input for policy and decision making and use of Artificial Intelligence as a tool to process large amounts of data and draw informed conclusions for policy making. In 2023, two activities have well advanced: (i) automatic cataloguing of data already available in the current SANTE IT systems and solutions; once fully in place, it will empower users to identify data and create their own simple reports as well as publish data automatically using data pipelines to the EU open data portal; (ii) identification and sharing of information amongst DG SANTE and its agencies (HPAC members). As the results from the pilot on pesticides data sharing with EFSA in 2023 were positive, DG SANTE intends to use this pilot as the blueprint for sharing other information on health and food sustainability with the different agencies during 2024.

2.1.3 Economy of controls

The main economy indicators monitored in 2023 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 calculated on an all-cost basis without including an overhead rate. They are based mainly on estimates made in the Unit Management Plans approved by the Director-General (for more detail on the indicators see Annex 7.2).

Table 2.4 Economy of controls – evolution over time

Cost of controls as % of annual payments	Targets	2023		2022	
		Payments M€	Cost of controls %	Payments M€	Cost of controls %
Grants to Member States in the Food Safety policy area	< 5%	154.5	1.0%	47.9	3.1%
Public procurement and other grants	< 7%	62.6	5.5%	85.7	3.7%
Contribution agreements, mainly with international organisations ¹¹	< 5%	24.1	4.6%	-	-
Subsidy payments to agencies	< 1%	347.8	0.4%	333.6	0.4%
Total		589.0	1.3%	467.5	1.3%

In 2023, DG SANTE implemented a large part of its budget of the SMP-Food chain strand through grants co-financing Member States' veterinary and plant emergency measures. The management of these grants is particularly demanding, the main cost-drivers being the

¹¹ Contribution agreements with EU decentralised agencies are grouped under this control system. Contribution agreements are reported separately for the first time in 2023. In the 2022 AAR, they were included in "public procurement and other grants"

diversity and complexity of the files in both technical and financial aspects. While the costs of controls remained relatively stable in 2023, the cost indicator for grants dropped to 1% due to the high amount of pre-financing payments made in 2023.

Public procurement procedures initiated in 2023 were oriented to the implementation of the MFF budget for Health and for Food Safety. Public procurement is highly regulated. That means, compliance and good quality must be ensured in each process. For many years, DG SANTE has purchased services in new fields and technically complex environments entailing a relatively high workload for drafting tender specifications. Contract values are usually relatively small which increases the indicator “cost over payments made”. Grouped under procurement are the control costs for safeguarding of assets as they are marginal and not attributable to a separate control system.

DG SANTE concludes contribution agreements only with international organisations that have been pillar assessed. As DG SANTE does not conduct pillar assessments itself but relies on assessments conducted by other DGs, the cost of control reflects the diversity of a relatively large number of agreements each with relatively complex technical preparations and monitoring of the work performed by the international organisations.

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.

2.1.4 Conclusion on the cost-effectiveness of controls

Based on the most relevant key indicators and control results, 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 considers that its control strategy for grants, public procurement, contribution agreements to international organisations and subsidy payments to agencies 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, the low error rate since several years and the timely payments.

2.2 Audit observations and recommendations

This section sets out the observations, opinions and conclusions reported by auditors – including the limited conclusion of the Internal Auditor on the state of internal control. Summaries of the management measures taken in response to the audit recommendations are also included, together with an assessment of the likely material impact of the findings on the achievement of the internal control objectives, and therefore on management’s assurance.

2.2.1 Internal Audit Service of the Commission

The IAS contributed to DG SANTE's Annual Activity Report for 2023 by submitting a "limited conclusion on the state of internal control" in February 2024. Based on the audit work performed in the period 2019 to 2023, 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 8.1.2).

DG SANTE believes that thanks to the mitigating measures already put in place in 2023, 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.

2.2.2 European Court of Auditors

(a) 2022 DAS – compliance audit

In October 2023, the Court published its annual report (2022 DAS) on the implementation of the EU budget for the 2022 financial year. The structure of the Court's 2022 report is adapted to the budget headings of the Multi-annual Financial Framework (MFF) 2021-2027. DG SANTE is part of the policy chapter 5 "Cohesion, resilience and values". In its report, the Court did not raise a finding on DG SANTE's budget implementation.

(b) Court's special reports of 2023

In April 2023, the Court published its review on "transport of live animals in the EU: challenges and opportunities". In its review, the Court highlighted trends in animal transport and draw attention to the challenges EU policy-makers face, as well as opportunities they can explore in the upcoming revamp of EU rules. The Court did not issue any recommendation for the Commission.

(c) Court's previous audit reports and DG SANTE's follow-up

DG SANTE addresses all audit recommendations by proportionate action plans and monitors their implementation regularly. Open recommendations relate to eight audits: food waste, animal welfare, food safety, cross-border health care, antimicrobial resistance (AMR), sustainable use of pesticides, protection of pollinators, and tools facilitating travel within the EU during the COVID-19 pandemic. Actions to address all open recommendations are well advanced with target dates for full implementation mostly in 2024. DG SANTE was able to close several recommendations by late 2023. Detail on the Court's recommendations and DG SANTE's follow-up actions are included in Annex 8.1.2.

The Director in charge of Risk Management and Internal Control (RMIC) reports on the progress made twice a year, firstly in the context of the mid-term report on internal control, and secondly during the annual activity reporting. DG SANTE's implementation of audit recommendations is in general assessed as positive: auditors find DG SANTE's actions appropriate and do not report any improper delays.

2.2.3 Conclusion on audit results and follow-up

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 pointed out in the IAS audits do not point to significant quantifiable errors. Furthermore, DG SANTE is confident that the elements identified could not seriously 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.

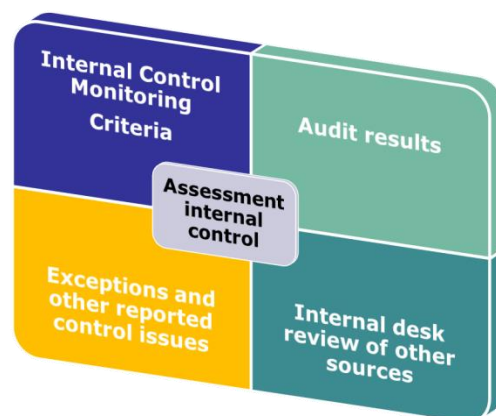
2.3 Assessment of the effectiveness of internal control systems

The Commission has adopted an Internal Control Framework based on international good practice, to ensure the achievement of its policy and management objectives. Compliance with the internal control framework is a compulsory requirement.

DG SANTE uses the organisational structure and the internal control systems suited to achieving its policy and internal control objectives in accordance with the internal control principles and has due regard to the risks associated with the environment in which it operates.

In its internal control system, DG SANTE embedded continuous monitoring measures to ensure that its management and internal control framework is effective. Assessing the effectiveness of its internal control system and its results, DG SANTE follows the methodology proposed in the “implementation guide of the internal control framework of the Commission”.

The assessment findings are evaluated and any deficiencies are communicated and corrected in a timely manner, with serious matters being reported as appropriate. The main sources of information and details of the assessment are described in Annex 8.2.



Throughout the year, the functioning of the internal control system was closely monitored by the systematic registration of so-called "exceptions", non-compliance events and internal control weaknesses. In each case, the underlying causes behind the exceptions and weaknesses are analysed and drawn to the attention of or submitted for approval of the Director-General (more detail is given in Annex 8.2).

DG SANTE has assessed its internal control system during the reporting year 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 ethics, staff allocation and professional development, functions that are only partially under DG SANTE management. In addition, further attention is warranted to improve DG SANTE's "change management" and certain elements of DG SANTE's control strategy.

The following actions have been and will be taken in this respect: an ethics and professional integrity awareness event for DG SANTE staff took place in June 2023, and further events will be organised in 2024 in close co-operation with OLAF, IDOC and DG HR. Further to its new organisational structure as of 1 October 2022, DG SANTE invested heavily in filling seven vacant senior management posts of which 30% (3 posts) remained vacant in 2023. With its reorganisation, DG SANTE achieved an improved balance of workload between Units, although the available human resources still fall short of the needs for realising the many policy initiatives in DG SANTE's portfolio (for more detail on the management of human resources see section 3.1 below). The new organisation also required an update of DG SANTE's internal control strategy. This work had to be postponed from 2023 to 2024 due to other priorities; the update in 2024 will allow to take the new corporate guidelines of early 2024 into consideration.

In conclusion, no instances of ineffective controls came to management's attention that would have exposed the DG to serious risks. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance.

2.5 Conclusions on the assurance

This section reviews the assessment of the elements already reported above (in Sections 2.1, 2.2 and 2.3), and the sub-conclusions already reached. It draws an overall conclusion to support the declaration of assurance and whether it should be qualified with reservations.

The information reported in section 2.1 stems from the results of management and feedback received in audit reports listed above. These reports result from a systematic analysis of the evidence available. 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). The coverage of the Internal

Control Objectives and their related main indicators are described in more detail in Annexes 6 and 7.

Since the transfer of budget implementation tasks, including ex-post controls, to HaDEA in 2021, DG SANTE has not carried out ex-post controls anymore on the transferred grants. The last batch of previous audits in the policy area Food Safety was closed in 2022. Therefore, 2023 is the first year for which DG SANTE does not report on an error rate of ex-post controls anymore. For the grants not transferred to HaDEA and still implemented by DG SANTE, the internal control strategy provides for extensive ex-ante controls, mainly in the form of on-the-spot financial audits on grants to Member States for their emergency measures for animal and plant health. Based on past experience and HaDEA's ex-post control results related to Member States' animal and plant health programmes, DG SANTE estimates an equivalent to the detected error of just under 2% for grants to Member States for animal and plant health emergency measures. Future corrections are prudently estimated at 0%. As subsidy payments to agencies are based on reports of the Court of Auditors, the error rate is set at 0%. This results overall in an estimated overall risk at closure of about 1%. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance. Taking into account the conclusions of the review of the elements supporting assurance and the expected corrective capacity of ex-post controls to be implemented in subsequent years, DG SANTE assesses that it has an effective, efficient, robust and reliable internal control system at its disposal.

None of the issues raised by internal and external auditors met the qualitative materiality criteria: based on the audit engagements performed, their objectives and scope, 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.

Therefore, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General and thus, it is possible to conclude that the internal control system provides sufficient assurance with regard to the achievement of the other internal control objectives and no reservation to the declaration is warranted.

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 ⁽¹²⁾.

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 27 March 2024

(signature)

Sandra GALLINA

⁽¹²⁾ 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

After several years of intense crisis management, in 2023 DG SANTE consolidated the many policy initiatives launched from the lessons learned. The revision of the DG's organisational structure implemented in autumn 2022 allowed to a certain extent rebalancing the workload between Units, Directorates and geographical sites. However, despite the several internal redeployments carried out in 2023 there is still an important deficit between the resource need as indicated in the financial fiches of our initiatives and the resources available in the DG. Moreover, the absence of sufficient laureates of competitions, and the need to improve geographical balance of the staff has significantly increased the workload related to filling vacancies leaving very little scope for DG SANTE's local HR staff to invest in other domains of HR activity.

We have however been able to keep the vacancy rate low, at +- 6%, and to make progress on filling important gaps in the organisation chart by recruiting four new Directors and a new female Head of Unit. Five additional senior management selection processes have been started including from Agencies.

DG SANTE continued to focus on stimulating collaboration and communication. The Director General proceeded the practice of stimulating open communication lines with staff and managers of which the regular morning coffee sessions with the Director General, extended management board meetings and several SANTE senior management seminars examples. Added to these are the many DG SANTE knowledge hour discussions covering a diverse range of topics that keep the finger on the pulse of DG SANTE activities, stimulate the exchange of ideas and their uptake by the policy domains and ensure integration in the daily working processes of the DG.

Specific Live Webinars were organised on issues such as anti-discrimination & health equity and on a comprehensive approach to mental health contributing to one of the core values of the European Union namely to promote equality, diversity and inclusion. More action on these topics will take place in 2024. Managers are also encouraged to participate in the HR Middle Management Talks (20 meetings in 2023 on a broad range of topics) and the Middle Management Network meetings.

The above investments have clearly paid off as shown by the results of the 2023 Staff survey. The engagement of DG SANTE with 76% has never been higher than today.

Finally, as regards encouraging and facilitating mobility, 2023 showed that the impact of DG SANTE's aging population is slowly but surely requiring increasing efforts to maintain sufficient knowledge and experience in the different policy domains. In some Directorates more than 50% of the AD staff is over 55. Therefore, DG SANTE focussed on keeping a good mix of junior and experienced staff in the Units to ensure appropriate transfer of knowledge and thus business continuity.

3.2 Digital transformation and information management

a) Digital transformation

DG SANTE continues the work towards the Corporate Digital Strategy applying the "reuse-buy-build" approach for all digital transformation activities. We continue to rationalise and modernise our portfolio of digital solutions. Improving the security of our systems and data towards a strong cybersecurity position is an ongoing process well integrated in our annual work. Our AI task force has been delivering AI solutions for business needs and ensures alignment with and take up of corporate developments and tools. We have continued to implement the Cloud@EC strategy. All new systems (including CPMS and HealthData@EU) are built in the cloud and the cloud environment to accommodate existing systems is in place.

We have addressed the Commission Digital Strategy objectives as follows:

- Objective 1 DIGITAL CULTURE - digital talent and empowerment, we have delivered in collaboration with central services knowledge hours and info sessions on cybersecurity awareness, use and application of Artificial Intelligence for evidence that can be used in policy making (domains of Substances of Human Origins and Food Fraud) and we have co-delivered with DGT a seminar on Artificial Intelligence for all DGs. We also participate in corporate initiatives including AI@EC, as active contributors and ambassadors to deliver this new way of work back in SANTE. We have organised info sessions on modern ways of collaborative work including M365 and Teams and have established a SANTE champions network that meet on a weekly basis to share experience and needs.
- Objective 2 DIGITAL-READY POLICY MAKING – DG SANTE has been using its Data and Digital Steering committee (DDSC) to decide and steer all digital activities, putting emphases on digital ready policy making. Such has been the case for the eHealth Data Space (HealthData@EU) being in evolution together related policy developments. We have also been by pursuing further possibilities for digitalisation across DG SANTE and Member States in the domain of food sustainability, introducing more cases of digital certificates replacing manual procedures.
- Objective 3 DIGITAL TRANSFORMATION – DG SANTE has continued the modernisation and transformation journey. We have delivered Artificial Intelligence solutions for policy making in the Substances of Human Origin domain and Food Fraud monitoring. We have established a data lake and it is already used for collection and dissemination of data sets, including towards the Open Data Portal and provides services towards data analysis and results visualisation.
- Objective 4 SEAMLESS DIGITAL LANDSCAPE: DG SANTE applies and uses the Dual Pillar approach with a proper analysis in all digital investments. We have consulted central services and have launched the new ERN/CPMS and HealthData@EU central services projects to deliver systems in the cloud using or be made available as open source solutions. On the reuse of digital solutions we have completed the majority of developments reusing CASE@EC from DG COMP (integrated with HAN) to deliver the

SANTE IMSA solution. We have replaced all but 2 legacy solutions in SANTE, one awaiting for a corporate solution using SUMMA services and the second to be replaced by EUDAMED, a new SANTE solution under development.

- Objective 5 GREEN, RESILIENT AND SECURE INFRASTRUCTURE: SANTE has accomplished a 99% migration to welcome. We have advanced a lot with cloud adoption, having in place working systems and using the cloud as the default environment for all new SANTE systems development.

Information on the **degree of implementation of the most expensive IT solutions** in SANTE:

Information Management System for Official Controls including TRACES, ADIS and RASFF: Further automation and alignment of business processes on plant health domain in TRACES. Improved performance accommodating increase of user base and volume of digital certificates for safety and import purposes. ADIS Integration with the global alert system of the World Organisation for Animal Health (WOAH-WAHIS). Introduction of multi-factor authentication in RASFF, further securing the system. Establishment of business capability model for future RASFF and collaboration with central services towards a future corporate system for rapid alerts.

European Database for Medical Devices (EUDAMED): Completion of three modules of Actors, Devices and Certificates which are available for end users in industry and competent authorities, as planned. Ongoing implementation of vigilance and machine to machine exchange modules.

eHealth: European Reference Networks / Clinical Patient Management System (ERN/CPMS): Launch of fixed price contract to develop an open source cloud solution for future CPMS fully aligned with new Generation Digital Strategy. Establishment of the cloud infrastructure to support CPMS fully aligned with corporate services recommendations (Cloud Centre of Excellence). Project continues for the next 2 years before the system is fully operational. Collaboration with corporate eUI team towards needed developments to support eUI in mobile apps as CPMS has extensive needs.

eHealth: HealthData@EU central services: Performed an architectural design for HealthData@EU central services platform. Launch and conclude of open call for solution implementation using open source cloud technologies as foreseen by new Generation Digital Strategy.

b) Information and IT security rules

DG SANTE has a large portfolio of digital solutions and information which are mainly accessed from external stakeholders. We have in place a continuous process for cybersecurity and security rules. We perform periodic reviews on all IT security risks and update relevant plans and actions accordingly.

We have implemented Multi-Factor Authentication (MFA) for almost all our systems that have external access. For the three systems that are not using MFA, a justified compliance exception is in place.

We maintain security plans for all our operational information systems and we have verified that all security plans are less than two years old.

Cybersecurity is a crucial concern for DG SANTE, and we have been using ITSRM for security assessment and consequent plans for all systems with enforcing audits and improving the resilience of our digital solutions to mitigate against cyberattacks.

This approach is applied for all systems being developed internally or outsourced and hosted in the DIGIT Datacenter or in the Cloud in alignment with Cybersecurity recommendations of the Security Directorate.

c) Information management

DG SANTE's Data and Digital Steering Committee continued its mission as a central governance structure to steer and monitor decisions on data and digital related investments that support DG SANTE's policy objectives whilst looking forward to meeting the future needs of the DG. The Committee met three times in 2023. It endorsed the DG SANTE data strategy (later approved by the DG SANTE Management Board) and throughout the year monitored its implementation. The committee oversees and decides also all digital activities in SANTE.

The first year of implementation of SANTE Data Strategy mainly focused on mapping of the data needs, updating the list of SANTE data assets and raising awareness among DG SANTE staff. A project for a SANTE data lake and for automatic cataloguing of all Information Systems data has been launched, as well as a process for selecting valuable artificial intelligence projects. The pilots on SOHO and food fraud have delivered results and Considerations are given to a possible re-use in other areas.

DG SANTE acknowledges the close interlink between data and digital tools for managing them. Thus, relevant actions on data, information and knowledge management have been integrated into a common Data and Digital master plan.

d) Data Protection

In 2023, DG SANTE followed the five objectives specified in the Commission's Data Protection Action Planⁱ.

As every year, DG SANTE reviewed and updated existing records to ensure that they reflect the reality of the processing operation. The exercise focused in particular on precise description of processings carried out by DG SANTE, proper identification of legal bases and on correct application of retention periods (storage limitation). It also included mapping of possible access to DG SANTE IT tools and databases by other DGs, EU institutions or bodies and generally, particular attention was paid to the actual flow of personal data.

Awareness raising activities continued throughout the year with regular general trainings to newcomers and specifically designed individual trainings and information sessions that targeted particular areas of data protection rules and administrative practices that were needed for work of DG SANTE staff. Combined attendance of events on data protection awareness raising in DG SANTE reached 80% of all staff over the last four years. It is therefore expected that the 100% attendance on data protection awareness raising activities goal that was set up in DG SANTE's Strategic Plan will be achieved in 2024.

In 2023, based on the results of the Data Protection Impact Assessment on the Early Warning and Response System that was carried out in 2022, DG SANTE proceeded with the alignment of this system with the new applicable legislation.

DG SANTE also investigated and discussed with other Commission services (mainly Legal Service and DG JUST) the possible legal tools to be used for transfers of personal data of Ukrainian patients diagnosed and/or treated in EU back to Ukraine in the framework of the Early Warning and Response System or of the Clinical Patient Management System.

Moreover, DG SANTE collaborated with other DGs and the EC DPO Office in general data protection issues such as the whistleblowing and its impact on data protection, the allocation of responsibilities between the DGs, Access to Documents requests and data protection, etc..

3.3 Sound environmental management

The Commission's Political Guidelines for the period 2019-2024 recognise the importance of European Union leading role in reducing environmental impacts. In 2023, 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 the blended working arrangements became the "new normal", a section of the main office building in Grange remained shut throughout the year to continue reducing energy use. As in the previous year, the entire Grange site was shut down for an extended Christmas holiday period to leverage telework and achieve additional resource efficiencies. Many meetings and audits continued by video conferences.

In 2023, the use of VC meeting rooms increased considerably as compared to the year before. The environmental features of the site were significantly enhanced by the plantation of over 5,160 native trees, which not only enhance biodiversity, but over time will also create an additional carbon sink. Finally, "Building Energy Rating" certificates and advisory reports were obtained for the buildings in Grange, providing a better insight into their current energy performance and a useful input to future decisions on efficiency-related building improvements.

3.4 Examples of economy and efficiency

In its 2023 Management Plan, DG SANTE identified three initiatives to improve the efficiency and economy of its operations. The following progress was made in 2023:

1) Revision of the use of unit costs and lump-sums in the SMP

A revision of the financing system for EU support to Member States for veterinary and phytosanitary programmes and emergency measures in the Single Market Programme Food chain strand was launched in 2020 with the Joint Research Centre (JRC) in close co-operation with DG SANTE and the Health and Digital Executive Agency (HaDEA). After having authorised the use of lump sums in the veterinary programmes, lump-sums were also authorised for the phytosanitary programmes with decision on 22 February 2023. They were applied for the first time to the grants for 2023. The lump-sums are expected to reduce administrative burden and speeding up the payment process, allowing financial support to Member States against results rather than based on eligibility; maintaining a sound and coherent technical reporting on the activities carried out; as well as reducing the error rate.

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

The Commission prepares for the use of a new corporate financial tool, SUMMA, that will replace ABAC. In 2023, DG SANTE analysed and prepared its future budget structure, so that the SUMMA tool will answer DG SANTE's needs in terms of management, operational and financial objectives. The new SUMMA tool will combine robust security settings with the necessary flexibility in the budget implementation and will contain operational information supporting correct and reliable reporting. In 2023, DG SANTE spent considerable time in training and testing sessions organised by DG BUDG. The Supervisory Board decided postponing the go-live of SUMMA until 1 January 2025.

3) 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. In the course of this period, work has focused on technologies and capabilities for data cataloguing as input for policy and decision making and use of Artificial Intelligence as a tool to process large amounts of data and draw useful conclusions for policy officers. DG SANTE has launched two different activities: (i) automatic cataloguing of data already available in the current SANTE IT systems and solutions; once fully in place, it will empower users to identify data and create their own simple reports as well as publish data automatically using data pipelines to the EU open data portal; (ii) identification and sharing of information amongst DG SANTE and its Agencies (HPAC members). Following the positive results from the pilot on pesticides data sharing with EFSA in 2023, DG SANTE intends to use this pilot as the blueprint for sharing other information on health and food sustainability with the different agencies during 2024.

ⁱ C(2018)7432 and the review (C(2020)7625