



# Annual Activity Report 2022

DG Health and Food Safety (SANTE)

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## FOREWORD



*The COVID-19 pandemic that has impacted our lives so deeply is still with us. Happily, these days it casts a smaller shadow over our lives. It also continues to remind us of the interdependence between human, animal and plant health, and the need to view all health challenges through the 'One Health' lens.*

We are now in the age of pandemics, where climate change and environmental degradation heighten the risk of infectious diseases. The silent threat of anti-microbial resistance is growing louder. The burden of non-communicable diseases looms ever larger.

But COVID-19 has set the wheels of change in motion. To face these global challenges, we need global solutions.

In many instances, this Directorate-General has been on the front line. We have stepped up whenever called upon, proving ourselves adaptable in confronting these challenges and in seeking a better, healthier future for people.

We live in a changing world. We must change with it. In 2022 we took concrete steps to respond to the new realities we face.

A new Global Health Strategy, launched in November, will make global health the highest priority, striving for the highest health standards. At the same time, DG SANTE has maintained its central role in the Commission's coordination of the EU response to the pandemic, and in building resilience to future serious threats to health. Despite the challenges, DG SANTE has continued to deliver its work with quality, dedication, and perseverance.

The Green Deal and the Health Union remain the solid foundations on which we can build with confidence in the last stretch of the von der Leyen Commission. Other health achievements include publishing a proposal to revise the legislation on Blood, Tissues and Cells, and another to create a European Health Data Space; rolling out Health Technology Assessment legislation; and implementing the initiatives in Europe's Beating Cancer Plan.

We have kept on delivering on the Farm to Fork Strategy. We have put forward the Sustainable Use of Pesticides proposal and have carried out sizeable preparatory work on proposals linked to new genomic techniques, animal welfare, new EU food waste reduction targets and our sustainability framework.

Alongside these headline achievements, our daily work on authorisations, food safety and animal health has not stopped. It is a success in its own right, providing valuable contributions to our shared goal of making Europe a healthier, safer place for its citizens.

Each of us can be proud of what we achieved, as a team, in 2022. I count myself lucky to lead colleagues who have remained focused on the task at hand, despite being thrust into the limelight.

Now, as the Commission's current term enters the final straight, our reorganised Directorate-General is better equipped to face the future. Better able to adapt to the challenges of today and tomorrow. Together.

To all DG SANTE staff, I wish to extend my thanks for their hard work, enthusiasm, professionalism and resolve.

**Sandra GALLINA**, Director-General of DG SANTE

## THE DG IN BRIEF

DG SANTE 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 contributes to two of the general objectives set out in President von der Leyen's Political Guidelines – A **European Green Deal** and **Promoting Our European Way of Life**. Health and food safety and sustainability are of paramount importance.

DG SANTE plays a leading role in managing **cross border threats to health** at EU level, including the COVID-19 pandemic, by coordinating and supporting action to prepare for and respond to such threats.

We also manage EU health legislation which includes – among others – 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 e-health and rare diseases. Our activities in this area are both regulatory and 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 single, common regulatory framework, which aims to

ensure food safety 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 Commissioner for Health and Food Safety on the basis of multi-annual policies and financial frameworks.

The EU4Health Programme with a budget of EUR 835 million in the 2022 work programme is the main financial instrument to fund the Union health initiatives. The EU4Health

Programme continued to support the implementation of Union priorities such as the fight against the COVID-19 pandemic, the establishment of European Health Emergency Preparedness and Response Authority ('HERA'), Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe and the implementation of Union health legislation. The Emergency Support Instrument (ESI), which had been activated in 2020 – for only the second time since its creation in 2016 – to help EU countries address the COVID-19 pandemic, expired on 31 January 2022. On 28 July 2022, the Commission provided a [report to the Council and the Parliament on the implementation of the ESI](#), providing evidence of the good results achieved, in particular through the vaccine instrument, which consumed 70% of the ESI funds.

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, training and official control activities, including the financing of EU Reference Laboratories (EURLs), and relations with relevant international organisations. The total 2022 budget of the Food Safety strand of the Single Market Programme amounted to EUR 312 million for those 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 total limited budget, the co-financing rate for veterinary and phytosanitary programmes had to be decreased by 60%. This reduced rate will be implemented starting from 2023 programmes.

DG SANTE cooperates closely with the European Health and Digital Executive Agency (HaDEA) and HERA whose mission is to prevent, detect, and rapidly respond to health emergencies. DG SANTE is the lead DG for 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 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 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 two Deputies and Directorate and Unit managers, as well as weekly management meetings involving the Director-General and the Management Board are important monitoring activities.

In 2022 DG SANTE successfully reorganised its organisational structure to allow better embodying the "One Health" vision, to improve the workload balance between the different Units, Directorates and geographical sites and to properly integrate the heightened importance as a spending DG in the workflows. At the end of 2022 DG SANTE had 734 statutory staff and 57 seconded national experts.

DG SANTE pursues its policies with a focus on prudent management and protection of the EU's financial resources. The Director-General is the authorising officer by delegation and has sub-delegated budget implementation responsibilities to Directors and Heads of Unit.

About 32% of the 2022 budget was implemented under direct management, mainly through grants, procurement and 5% was implemented under indirect management through contribution agreements mainly with international organisations such as the International Federation of Red Cross and Red Crescent and the World Health Organisation (WHO). The remaining 63% constitutes subsidy payments to four EU decentralised agencies for implementing their tasks.

Risk management helps establish and maintain specific internal control strategies focussing on the activities and domains representing the highest risks. As in previous years, DG SANTE's centralised on-the-spot controls played a prominent role in the financial control environment, verifying – where applicable – the eligibility of costs claimed at beneficiary level in Member States.

In 2022, DG SANTE's results of ex-post controls lead to an estimated risk at closure of 0,7% and thus, did not exceed the materiality threshold of 2%. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance.

## 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 Treaties<sup>1</sup>.**

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

DG SANTE plays a key role in achieving the Commission's priorities in two crucial areas of EU citizens' lives – health and food. In doing so, it makes a significant contribution to two of the general objectives set by President von der Leyen – A **European Green Deal** and **Promoting Our European Way of Life**. As the COVID-19 pandemic receded in 2022, the Russian aggression against Ukraine came to dominate the year, affecting both global food security, and the mental and physical health of Ukrainian citizens, many of whom found themselves refugees in the European Union. DG SANTE was active in addressing both these urgent issues, as well as on many other fronts.

#### **1. A European Green Deal**

##### Farm to Fork Strategy

In 2022 DG SANTE continued to implement the Farm to Fork Strategy adopted by the Commission in 2020.

**Food security and sovereignty** were of course major issues in 2022, following the Russian aggression against Ukraine, and the return of cost inflation to levels not seen since the 1980s. DG SANTE sought to help find short-term solutions without sacrificing the long-term goal of transforming the European food system to meet the challenges of resource depletion and climate change. To this end, DG SANTE participated actively in the work of the European Food Security Crisis preparedness and response Mechanism and contributed to the Commission's analysis of the main drivers affecting food security that was published at the start of January 2023.

Work progressed towards the proposal for a **new legislative framework on sustainable food systems**, which is intended to lay down general principles and objectives that can ensure the integration of sustainability into all the EU's food-related policies. As part of the ongoing impact assessment, a large-scale internal study was commissioned, and a major public consultation was held from April to July.

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<sup>1</sup> Article 17(1) of the Treaty on European Union

In June the Commission proposed a new Regulation on the **sustainable use of pesticides** (SUR) to replace the existing Directive. The proposed Regulation would 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 improve the availability of sound data and statistics for evidence-based policy making. The proposal sets 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. At the end of 2022, the SUR proposal was in active discussion with the co-legislators.

Meanwhile, DG SANTE continued to work with the Member States to implement the existing legislation on pesticide use. The DG published a report in June which showed progress towards the Farm to Fork targets, but also confirmed the need to do more to **reduce dependency on pesticides** and improve the take-up of low-risk and non-chemical alternatives for plant health protection.

In 2022, DG SANTE continued to pursue the actions necessary to achieve the F2F Strategy's target of **50% reduction of the overall use of antimicrobials in animals**. Further steps were taken to implement the recent legal acts in this area, and the much-awaited list of antimicrobials that can no longer be used on animals, but only in human medicine, was published in July.

As part of its work to **reduce food waste** across the EU, DG SANTE is supporting the organisation of a **citizens' panel** in order to harness the insights of Europeans on how to step up efforts. The panel will help inform DG SANTE's work on food waste prevention including the forthcoming legislative proposal to set legally binding targets. This was the first time that such a citizens' panel had been organised by the Commission in relation to a future legislative initiative, and its recommendations will help guide the EU in pursuing its policy aims.

DG SANTE published its fitness check of the **Animal Welfare Legislation** (five EU Directives and two EU Regulations) which confirmed the need to strengthen and modernise the rules applicable to farming, transport and slaughter practice. An impact assessment was launched for the revision of the legislation, assess options for the introduction of animal welfare labelling and deliver on the Commission's commitment to phase out the use of cages for all the species referred to in the "End the cage age" citizens' initiative.

In international fora, DG SANTE steers the Commission's position on promoting 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 our **actions on the global stage**. DG SANTE continued to promote the Farm to Fork Strategy internationally during 2022, seeking to build "green partnerships" with likeminded non-EU countries, and pursued the inclusion of Sustainable Food Chapters (or related provisions) in the EU's Free Trade Agreements, such as those with Chile and New Zealand that were concluded during 2022. Relationships with Eastern Partnership countries were strongly affected by the war in Ukraine, and DG SANTE was intensely involved in EU actions to safeguard global food security, in particular for those countries (mainly in North Africa and the Middle East) which are heavily dependent on cereal imports from Ukraine and Russia.

## Food and feed safety

In 2022 DG SANTE continued to oversee the mandatory **authorisation and approval procedures** for products and substances used in food and feed production and processing that are placed on the EU market. In January, a Regulation was adopted by the Commission which banned the use of titanium dioxide (a colouring agent) as a food additive, after EFSA published an opinion which could not rule out concerns regarding genotoxicity. In April 2022 the outdoor use of Sulfoxaflor, a chemical pesticide, was banned because of potential adverse impacts on wild pollinators. Meanwhile, the debate around the potential renewal of glyphosate continued throughout the year, generating an unprecedented number of comments from European citizens which led EFSA to inform the Commission that it would not be able to conclude peer review of its assessment report until mid-2023.

DG SANTE actively continued to pursue an integrated approach to the **prevention, control and eradication of animal diseases**, and to the **protection of the EU against plant pests and diseases**. The widespread outbreaks of Highly Pathogenic Avian Influenza and of African swine fever continued throughout 2022 and demanded swift action by the Commission to counter the spread of the disease while minimising impacts on non-affected regions. New and updated measures against *Anoplophora chinensis* and other plant pests were adopted and adjusted in line with DG SANTE's ongoing assessment of the risk they posed.

DG SANTE continued work on the impact assessment for the revision of the EU marketing legislation on seed and other **plant reproductive material**, supported by a [public consultation](#) which ended in March 2022. In parallel, and following on from last year's study on **new genomic techniques**, DG SANTE also launched an impact assessment on possible options for the deliberate release and marketing of plants obtained by targeted mutagenesis and cisgenesis and of food and feed products derived from them. To provide input for the impact assessment, a public consultation ran from April to July, and collected over 2000 responses from citizens and other interested parties.

In September, the Commission adopted a Commission Regulation on **recycled plastic** materials and articles intended to come into contact with foods. This regulation will facilitate the uptake of recycled plastics by the food packaging industry, which accounts for a major part of plastic packaging. The reinforced legal certainty over the rules applicable to plastic recycling represents a significant contribution to the Commission policy on the Circular Economy.

## **2. Promoting our European Way of Life**

The Russian aggression on Ukraine and people displaced from Ukraine had devastating consequences for the physical and mental health of Ukrainian citizens. DG SANTE played an important role in the EU's initiatives, in collaboration with many other national and international actors, to mobilise resources both inside Ukraine, and within the EU, to support those who were impacted by the ongoing violence.

Under the **EU4Health Programme**, the Commission signed a contribution agreement with a value of EUR 20.4 million with the International Federation of Red Cross and Red Crescent

Societies to provide mental health and psychosocial support to persons fleeing Ukraine. On 14 January 2022 the Commission adopted the second annual work programme for EU4Health with a budget of EUR 835 million. The third annual work programme for 2023 was adopted by the Commission on 21 November 2022 with a budget of EUR 735.8 million.

### Diminishing the impact of cancer in Europe

A key priority of the von der Leyen Commission, the **Europe's Beating Cancer Plan** was established in 2021. To mark World Cancer Day 2022, SANTE held its annual event, including the launch of four new actions under the Plan, ranging from a joint action with Member States on Human papillomavirus (HPV) vaccination, to an EU Network for Youth Cancer Survivors. To improve early detection, new updated EU cancer screening recommendations were presented.

As part of its fight against the single largest avoidable health risk in the EU, DG SANTE also continued work on the evaluation of **the Tobacco Products Directive and the Tobacco Advertising Directive**. The publication of a call for evidence in May received over 24,000 contributions from stakeholders and the public.

DG SANTE also continued its work on Healthier Together – an initiative to support EU countries in reducing the burden of the main **Non-Communicable Diseases**. 2022 also saw a renewed focus on **mental health** as a public health issue. The Commission launched a new comprehensive, prevention-oriented approach which will mainstream mental health into EU policies, as announced by President von der Leyen in her September State of the Union speech. A Communication to present the strategy is expected to be ready, following wide consultation with citizens and stakeholders, by the middle of 2023.

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

In 2022, 103 new medicinal products for human use were authorised in the EU by the Commission, of which 53 included a new active substance.

Under the 2020 Pharmaceutical Strategy for Europe, DG SANTE continued to work on its proposal for a major revision of the EU pharmaceutical legislation, which it now expects to adopt in April 2023. Two impact assessments, on the general legislation and the legislation on medicines for rare diseases and children, were finalised during 2022. The proposed revision aims to ensure the authorisation of high-quality medicines and that the EU has an adequate supply of affordable medicines to meet its needs whilst helping the European pharmaceutical industry remain an innovator and world leader.

In January, the new **Health Technology Assessment Regulation** entered into force, creating a legal framework for Member States to cooperate on joint clinical assessments of medicinal products and medical devices, and so strengthening EU capacity by eliminating the current fragmentation of work, shortening the time that new technologies take to reach patients, and fostering innovation and investment in this area.

2022 was a crucial year for the implementation of the **Medical Device Regulation** (MDR) and the **in vitro Diagnostic Medical Devices Regulation** (IVDR), and a lot of work was conducted to ensure availability of critical devices across the EU. In January, the European

Parliament and the Council adopted a Regulation allowing for a progressive roll-out of some provisions of the IVDR. Capacity and preparedness remained the main focus throughout the year for all concerned. An action plan including 19 mitigating measures was endorsed by the Medical Device Coordination Group in August 2022, and when this appeared not to be sufficient, DG SANTE worked intensively on a legislative proposal to extend the transitional deadlines in a staggered approach. This proposal was adopted in January 2023.

### Effective response coordination to serious cross-border health threats

The three legislative proposals made by the Commission in 2021 to strengthen Europe's resilience in the face of **cross-border health threats** were all adopted by Council and Parliament in 2022: a Regulation on serious cross-border threats, and Regulations strengthening the mandates of the ECDC and EMA to ensure that these Agencies are well equipped to respond to the challenges posed by future emergency situations. The result is a stronger and more comprehensive legal framework for the Union to better prevent, prepare and respond to serious cross-border threats to health as well as to other public health emergencies.

As the acute phase of **Covid-19** began to recede, attention increased in 2022 on the consequences of the pandemic, in particular on "long-covid" syndrome, on which DG SANTE hosted a virtual conference in December. Meanwhile, DG SANTE continued to deliver on the EU Strategy for COVID-19 vaccines. During 2022, the Commission authorised two new Covid vaccines, as well as the first two COVID-19 booster vaccines adapted to the different Omicron variants.

DG SANTE also continued to contribute to the work of the **COVID-19 vaccine global access facility**, COVAX, to ensure that vaccines are distributed equitably among participating countries according to the guidelines developed by WHO.

DG SANTE partnered with DG INTPA to develop **a new EU global health strategy** which was adopted by the Commission in November. This strategy is a response to the challenges that have emerged in recent years, including the Covid-19 pandemic, the increasing effect of climate change and biodiversity loss, and the evolution of infectious and non-communicable diseases. Work also continued with the EU's global partners on an **international treaty on pandemic prevention, preparedness and response**, and September 2022 saw the official launch of the Pandemic Fund in whose creation the Commission, including SANTE, played a key role. DG SANTE was very active in the intergovernmental negotiating body established to draft and negotiate this new instrument that is scheduled for adoption in 2024.

### 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.

In May, the Commission adopted a proposal for a Regulation on the **European Health Data Space (EHDS)**, with the goal of empowering citizens to control the use of their health data and offer a trustworthy framework for the use of health data for research, innovation and regulatory activities. This initiative is one of the central building blocks of the European

Health Union. The EHDS will be a key contributor to the patient-centred modernisation of health systems across the EU. As part of this, the cross-border exchange of **patient summaries** and **ePrescriptions** through the MyHealth@EU platform was extended with support from EU funding, with the number of Member States participating now rising to 11, and additional services launched.

Major users of the digital solutions provided by EHDS are the existing 24 **European Reference Networks**, which now bring together more than 1600 specialised healthcare providers.

In July the Commission adopted a proposal for a new Regulation accompanied by an impact assessment with a view to further increasing the safety and quality of **substances of human origin** used in the EU. With this proposal, citizens will be safer when donating or receiving vital substances of human origin (SoHO), from blood to tissues and cells.

The 4th cycle of the publication series “**State of Health in the EU**” was launched in 2022, continuing to provide high-quality, evidence-based analysis and information on health systems performance in the EU countries while also informing DG SANTE’s contribution to the **European Semester** and the **Recovery and Resilience Facility**. The 2022 edition of “Health at a glance Europe” was published in December, focusing on the impact of the COVID-19 pandemic on the health of children and young people, as well as on the pandemic’s impact on health services for non-COVID patients.

Monitoring of the implementation and enforcement of EU legislation

In 2022, DG SANTE has again delivered a significant programme of controls in order to monitor the implementation and enforcement of EU legislation, in both the food and health policy domains. In the food area, this resulted in 195 controls (including 149 audits) both in EU countries and non-EU countries exporting to the EU, to verify compliance with the EU requirements, and to issue recommendations in case of identified shortcomings.

**B. Key Performance Indicators (KPIs)**

**KPI 1: Diminishing the impact of cancer in Europe**

<p><b>Result indicator 2.1.A: Age-standardised five-year net survival of cervical, breast and colorectal cancer</b>  <b>Explanation:</b> 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.  <b>Source of data:</b> EUROCARE (Joint Research Centre) and CONCORD Programme, London School of Hygiene and Tropical Medicine</p>			
<b>Baseline (2014)</b>	<b>Interim Milestone (2022)</b>	<b>Target (2024)</b>	<b>Latest known results (2022)</b>

<b>Cervical cancer: 63% (EU average)</b> <b>Breast cancer: 83% (EU average)</b> <b>Colorectal cancer: 59% (EU average)</b>	<b>Increase</b>	<b>Increase, with at least 2/3 of Member States above baseline</b>	<b>Latest results available from 2014*</b>
	<b>Increase</b>		
	<b>Increase</b>		

\*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

<b>Objective: The authorising officer by delegation has reasonable assurance that resources have been used in accordance with the principles of sound financial management, and that cost-effective controls are in place which give the necessary guarantees concerning the legality and regularity of underlying transactions</b>		
<b>Indicator 1: Estimated overall risk at closure based on the error rate found by DG SANTE's on-the spot controls (ex-post) of payments made (calculated as "estimated overall amount at risk at closure"/"relevant expenditure")</b> <b>Source of data:</b> Internal follow-up sheet, reported in AAR		
<b>Baseline</b>	<b>Target</b> (according to the control strategy approved by the DG)	<b>The latest data</b>
2018: 1,0% (M€4.4/M€441.3)	Less than 2%	<b>2021: 0,7%</b> (M€ 12/M€ 1792) <b>2022: 0,7%</b> (M€ 6,6/M€ 1018)

DG SANTE carries out ex-post controls on a sample of payments made to Member States based on their cost declarations in the policy area "Food and Feed Safety". A key indicator of the legality of these payments is the estimated overall risk at closure which is calculated based on the average error rate detected or estimated and the corrective measures taken, such as the recovery of over-payments.

In the past years, DG SANTE has taken a series of mitigating actions, such as the use of unit-costs and lumps-sums, which reduced the error rate to an acceptable level. As the overall risk at closure does not exceed the threshold of 2%, no reservation to the declaration of assurance is warranted.

### C. Key conclusions on Financial management and Internal control (executive summary of section 2.1)

**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 Section 2.1.3 and Annex 8.2 for further details.

**In addition, DG SANTE has systematically examined the available control results and indicators, including those for supervising 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 2.1 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** on the deficiencies mentioned above. **The following actions were taken in this respect:** ethics and professional integrity awareness event for DG SANTE staff took place in January 2022, and further events will be organised in 2023 in close co-operation with OLAF, IDOC and DG HR; DG SANTE's organisational structure was revised as of 1 October 2022; an awareness event on internal control for DG SANTE staff and the update of DG SANTE's internal control strategy are planned for 2023. **The Director-General, in her 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 the DG 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

In addition to the actions reported on in this Chapter, DG SANTE manages a vast legislative *acquis*, on the basis of which several hundreds of delegated and implementing acts are adopted every year. Details of this important implementation work are given in Annex 2.

In 2022, SANTE continued supporting corporate communication linked to the COVID-19 pandemic, as well as the health response to the invasion of Ukraine. In addition, SANTE's communications actions took on an increasingly citizen-oriented focus, in addition to the traditional media and stakeholder audiences. In particular, awareness-raising campaigns on sustainable food systems and cancer helped to highlight key priorities for the Commission. Details of these and other communication actions can be found in Annex 2.

## 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 all contribute significantly to the European Green Deal. In 2022, 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. Simplification of the existing regulatory framework was also pursued whenever possible – as an example, we cite the preparation of a new Commission Regulation on maximum levels of contaminants in food replacing and consolidating the existing Regulation 1831/2003 which had been amended 45 times. (For more information on simplification initiatives, see Annex 2, Result Indicators 1.1.D and 1.1.E).

**Ensuring animal health and managing and isolating outbreaks of major animal disease.** In 2022, DG SANTE continued to actively pursue [an integrated approach to the prevention, control and eradication of animal diseases](#) that may be transmissible either to animals or to humans. On the prevention side, there was a significant increase of over 21% in disease-free statuses obtained in 2022, mainly due to the compulsory eradication programmes introduced by the Animal Health Law, to which Member States responded positively.

Outbreaks of major animal diseases did not relent in 2022 with two diseases, [African swine fever \(ASF\)](#), and [highly pathogenic avian influenza \(HPAI\)](#), requiring continuous efforts to ensure effective control and eradication. Special control measures for ASF and emergency

measures for HPAI were adopted and regularly reviewed to adjust their geographical scope so as to counter the spread of the disease while minimising impacts on unaffected regions. (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%.

In 2022 SANTE continued to ensure the smooth implementation of the [EU Animal Health Law \(AHL\)](#) which provides the regulatory framework to fight transmissible animal diseases. 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 [Commission Implementing Regulation on the registration of establishments keeping terrestrial animals, which was adopted in August 2022](#), enables Member States to allow derogations from an obligation to register certain establishments based on an assessment of the risk that they present. This represents a real simplification, for example, for small-scale establishments that only keep small numbers or poultry. DG SANTE also continued its support to Member States through the [Better Training for Safer Food \(BTSF\)](#) programme. In 2022, there were nine training sessions on the AHL (four virtual and five in real life) with over 250 participants from EU MSs, EEA as well as candidate and potential candidate countries. In addition, four sessions on animal disease preparedness took place in 2022.

**Preventing plant pests.** New threats emerging from climate change and globalisation have increased the risk of plant pest infestations. DG SANTE manages the [Plant Health Law \(PHL\)](#) to protect crops, fruits, vegetables, flowers, ornamentals and forests against new pests and diseases, which 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 with seven implementing acts adopted in 2022. New and updated measures were adopted for quarantine pests through the adoption of three containment measures, four potato control measures and measures against *Anoplophora chinensis*. Existing emergency measures were updated to take account of the latest science. More strict requirements have been introduced for the import of host plant material (including citrus fruits) to protect the Union territory against *Thaumatotibia leucotreta*. (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 2022 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. 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. Lower maximum levels for mercury in fish, and ochratoxin A in several foodstuffs, and new maximum levels for perfluoroalkyl substances (PFAS) in fish and food of animal origin, were adopted 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).

In January 2022, a Regulation was adopted by the Commission which [banned titanium dioxide \(also known as E171\) as a food additive](#), based on an opinion which EFSA published in May 2021 which could not rule out a possible risk to health, and in particular, genotoxicity concerns.

In April 2022 the [outdoor use of Sulfoxaflor](#), a chemical pesticide, was banned because of potential adverse impacts on wild pollinators.

The potential renewal of glyphosate continued to be a focus of activity throughout 2022. In light of the unprecedented number of comments received by EFSA on the [draft assessment report](#), and following its request for additional information from those applying for renewal of its approval, EFSA [delayed the delivery of its peer review to July 2023](#). In line with its obligations under the Plant Protection Products Regulation, on 2 December 2022 the Commission [therefore extended](#) the duration of the current approval of glyphosate by one year in order to allow for the completion of the evaluation.

SANTE also oversaw the implementation of [the new EU Regulations on veterinary medicinal products and medicated feed](#) that came into application on 28 January 2022, and which are key to achieving the objectives set in the European One Health Action Plan and in the Farm to Fork Strategy against antimicrobial resistance (AMR). DG SANTE continued to prepare the delegated and implementing acts necessary to their full implementation.

### **Performing effective, efficient and reliable controls**



In March 2022 DG SANTE published a report on official controls on food and feed, animal health and welfare, plant health and plant protection products performed in 2019 and 2020 in EU countries. For the first time, the report contains standardised EU-wide statistical data and (info)graphs showing the total number of business entities operating in the food chain, the number of official controls performed by national authorities, the number of non-compliance cases detected and of enforcement actions taken.

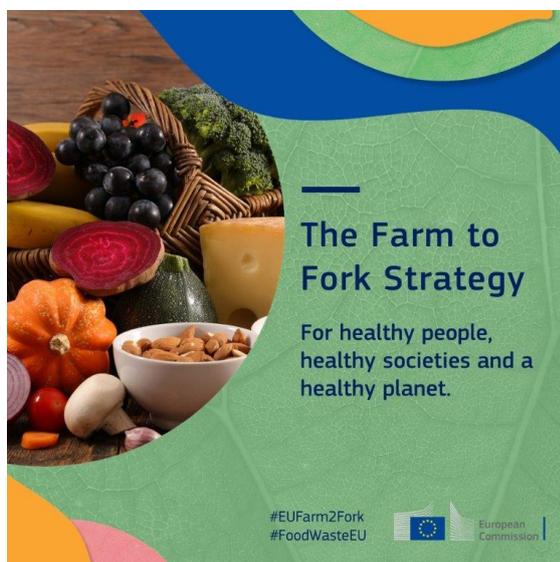
DG SANTE has further complemented and updated the legal framework on official controls with rules on border checks and on control

programmes for monitoring of residues of veterinary medicines that should be implemented by third countries exporting to the Union (adopted in July and September 2022 respectively). These steps will help improve the cost-effectiveness of residue monitoring through risk-based control plans on all EU produced and imported veterinary medicines.

DG SANTE continued to carry out controls, including audits, in both EU countries (122 controls) and non-EU countries (73 controls) that export to the EU to verify compliance with the EU's food chain requirements, and to issue recommendations in case of identified shortcomings. At the end of 2022, verified corrective actions had been taken by the Member States in response to 65% of the audit recommendations addressed to them in the period 2018-2020 (See Annex 2, Result indicator 1.1.C). All recommendations remaining open at the end of 2022 continue to be monitored by DG SANTE for progress.

**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 the Trade Control and Expert System (TRACES) with certain EU alert systems (e.g. RASFF and EUROPHYT). In 2022, for example, an international outbreak of Salmonellosis in children was linked to a popular brand of chocolates. The RASFF was instrumental for countries inside as well as outside the EU to communicate rapidly about this, and for the Commission, EFSA and ECDC to monitor the events and coordinate responses to the incident.

### **Specific Objective 1.2: Sustainable food systems – the 'Farm to Fork' Strategy**



In 2022 work continued on the preparation of a legislative proposal establishing a framework for a Union sustainable food system. This [flagship initiative of the Farm to Fork Strategy, jointly led by SANTE, AGRI, ENV and MARE](#) aims to translate the new concepts, objectives and parameters of food system sustainability into a framework legislation. Work progressed in 2022 on the impact assessment that will accompany the proposal for the new framework law. DG SANTE organised a public consultation from April to July which attracted over 2,600 contributions, some 80% of which came from citizens. An awareness-raising campaign was

organized on the VICE media portal from September to December under the heading “What the food”, which successfully attracted over four million views.

Since the launch of Russia's aggression against Ukraine, discussions around food systems have focused on the immediate importance of food security and sovereignty. DG SANTE has been actively participating in those discussions to find solutions to immediate short-term issues, but without losing sight of the long-term objective of transforming the EU food system so that it can meet the global challenges of climate change and resource depletion, and thus deliver on the European Green Deal commitments.

DG SANTE actively participated in the European Food Security Crisis preparedness and response Mechanism (EFSCM) which [started its work in March 2022](#), and will carry out a thorough mapping of risks and vulnerabilities of the EU food supply chain, followed by recommendations and appropriate mitigation measures. DG SANTE also actively contributed to the work led by SG on an analysis by Commission services of the main drivers affecting food security. The study, published on 4 January 2023, looks at the effects on food security of drivers such as climate change, environmental degradation, the economic consequences of COVID-19 and Russia's invasion of Ukraine.

DG SANTE also actively contributed to the work led by DG AGRI to assess the National Strategic Plans (NSPs) for the Common Agricultural Policy (CAP) as regards certain Farm to Fork objectives. All NSPs were approved in 2022.

### **Reducing dependency on and promoting the sustainable use of pesticides.**



The [proposal for a Regulation on the Sustainable Use of Pesticides \(SUR\)](#) revising the Sustainable Use Directive was adopted in June 2022. Its aim is 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 June 2022 SANTE published an [updated report on progress towards achieving the Farm to Fork targets](#) for the period 2011-2020 showing a continued reduction in risk and use of chemical pesticides in the EU with 2020 marking the second consecutive year with a meaningful reduction in the use of more hazardous pesticides. While these results are encouraging and confirm that the Farm to Fork pesticide reduction targets remain realistic and achievable, they also show that Member States need to do more to reduce the use and risk of chemical pesticides.

While the SUR proposal is being discussed with the co-legislators, 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. Targeted audits concerning the application of the Directive and the authorisation, marketing and use of pesticides in Member States were carried out.

In addition, DG SANTE continued in 2022 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, [four](#)

[implementing Regulations](#) amending data requirements, approval criteria and assessment methodologies for micro-organisms were adopted in September which will simplify and thus accelerate access to such biological alternatives. DG SANTE also conducted extensive preparatory work for an implementing Regulation laying down common rules for the records of the use of pesticides to be kept by professional users. The new rules will modernise and harmonise record-keeping through the obligation to record the data in an electronic format so as to facilitate the [collection of the data by the Member States' authorities for statistical purposes](#) and for monitoring the correct use of authorised plant protection products.

Responding to a request by the Council, DG SANTE prepared a report on invertebrate biological control agents, a possible alternative to chemical pesticides. Supported by an external study, the report looks at the market situation, the current (limited) uses of these agents, and the challenges behind and drivers for the limited uptake.

**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 such as the preparation of an Implementing Regulation setting out a procedure and criteria for the identification of co-formulants that are unacceptable in plant protection products.

**Reducing the use of antimicrobials in animals to contribute to the fight against AMR.** In 2022, 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 47% from 2011 to 2021, bringing us closer to the EU Farm to Fork target. In only 3 years (2018-2021), EU Member States have already reached approximately one third 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 a number of core measures to combat AMR. In particular, the list of antimicrobials which can no longer be used in veterinary medicine and can now only be used in human medicine was [published in July](#).

**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. In April the Commission [approved for marketing in the EU](#) an innovative feed additive consisting of 3-nitrooxypropanol, which will help to reduce the emission of methane, a potent greenhouse gas, from cows, thus contributing to the achievement of the EU's ambitious targets in the fight against climate change.

While work continued to finalise the evaluation of the Feed Additives Regulation, it was considered that more research was still needed to develop the impact assessment supporting the envisaged revision of the Regulation and to ensure the preparation of a solid evidence-based legislative proposal.



## Reducing food loss and waste.

The European Union is [committed to reaching the United Nations Sustainable Development Goal Target 12.3](#) of halving per capita food waste at retail and consumer levels by 2030, while also reducing food loss across the supply chain. Under the Farm to Fork Strategy,

the Commission aims to introduce legally binding targets to reduce food waste across the EU in 2023 and to revise the EU rules on date marking ('use by' and 'best before' dates). Work progressed on the impact assessment that will support the adoption of food waste reduction targets as part of a wider proposal amending the [Waste Framework Directive](#) led by DG ENV. The [public consultation](#) launched in May to gather views on the setting of such targets attracted over 700 contributions mainly from EU citizens, companies and business associations who in their great majority strongly supported the setting of legally binding targets. The Commission organised a **citizens' panel** in order to exchange views with citizens and harness their insights on how to step up action to reduce food waste in the EU. The citizens' panel met in its first session in December 2022. This was the **first time** that a citizens' panel was organised to **support a future legislative initiative**, and its recommendations will serve as a guide to help Member States in achieving these targets.

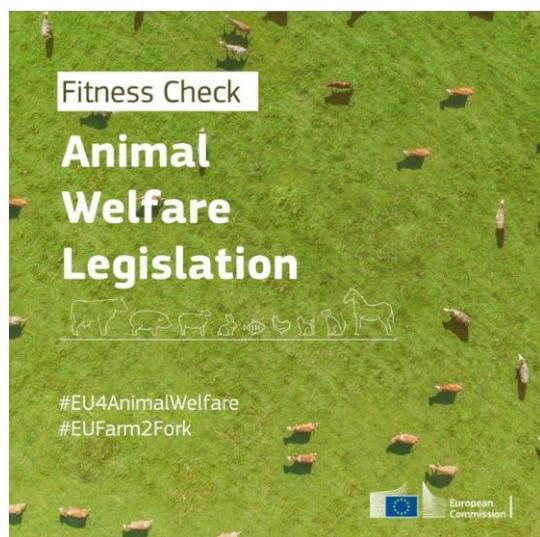
DG SANTE also re-established, in 2022, the [EU Platform on Food Losses and Food Waste](#) for a second 5-year term until 2026, with new members from private sector organisations selected following a call for applications. DG SANTE actively contributed to international work in food loss and waste prevention, including through the [Champions 12.3 network](#).

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

Good treatment of animals is an integral part of sustainable food production. In October 2022, SANTE published the [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). The report [confirmed the need to revise and modernise the EU animal welfare legislation](#). In particular, of the 60,000 citizens who responded to the public consultation carried out to support the fitness check, 80% demanded that the Commission introduce requirements for the welfare of dogs and cats. An impact assessment is ongoing to support the revision of the existing animal welfare provisions (on transport, farming, slaughter), assess options for the introduction of animal welfare labelling and deliver on the [Commission's commitment to ban the use of cages in animal farms](#).

DG SANTE's management of the [EU Animal Welfare Platform](#) directly supports the implementation and revision of the legislation. New subgroups of the platform that have been created to work on animal transport, on the welfare of pigs, poultry, calves and dairy cows, on animal welfare at the time of killing and on labelling, started work in March 2022 and they are providing expert input for the revision of the animal welfare legislation.

In 2022, DG SANTE continued to ensure the supervision of the Animal Welfare Reference Centres and started work to establish a Reference Centre for the welfare of fish in aquaculture during 2023. Two pilot projects on laying hens and dairy cows have also been pursued. The report on the best practices for keeping laying hens out of cages has been finalised and will be further disseminated in 2023. Two new pilot projects on stunning methods for pigs and on the monitoring of pig tail-docking indicators at slaughterhouse were launched.



To respond to the outcomes of the EP Committee of Enquiry on Animal Transport and in particular to increase the quality of the official controls in case of the transport of animals on livestock vessels work progressed towards the adoption of tertiary legislation.

A [report on measuring animal welfare at farm level](#) published by the Commission in 2022 highlighted that most national authorities have difficulties to implement effective systems to monitor compliance trends over time and that establishing specific and appropriate animal welfare indicators for different farming systems

and different production sectors could help in the production of more reliable data.

**Fighting against food fraud.** In 2022, DG SANTE continued to work with the Member States on actions directed at combating agri-food fraud, in particular through the launch and management of coordinated control plans on honey adulteration with extraneous sugars, on plastic tableware made of illegal fillers (bamboo fibres) and on [illegal trade of pets](#), and in contributing to OLAF, Europol and EUIPO operations and investigations. Fact-finding studies to two Member States were carried out.

**Empowering consumers to make sustainable and healthy food choices through the provision of food information.** In 2022, DG SANTE continued to work on an impact assessment to support a possible revision of the EU rules on food information to consumers. This work looks at a number of possible changes in EU legislation applicable to front-of-pack nutrition labelling, the setting of nutrient profiles to restrict claims, the extension of origin indication to certain products, a revision of the rules on date marking ('use by' and 'best before' dates) and the labelling of alcoholic beverages, as announced in the Farm to Fork Strategy and Europe's Beating Cancer Plan. In December 2021, a [public consultation](#) was launched, which ran until March 2022, and received over 3000 contributions, of which 65% came from citizens.

**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 also authorised a few insect species as novel foods (4 as of January 2023).

EUs agri-food production was supported in 2022 by the introduction of 2000 new varieties of agricultural and more than 1300 new varieties of vegetable species in the Common Catalogues, amounting to over 44 000 varieties.

DG SANTE continued work on the impact assessment for the revision of the EU marketing legislation on seed and other plant reproductive material; a [public consultation](#) which ended in March 2022 gathered feedback from the public and stakeholders on the proposed revisions. Over 2000 responses were received and analysed.

Following on from 2021's study on new genomic techniques, in 2022 DG SANTE started work on an impact assessment considering possible options for the adoption of specific rules on the deliberate release, including the placing on the market, of plants obtained by targeted mutagenesis and cisgenesis, and their food and feed products. To provide input for the impact assessment, a [public consultation](#) ran from April to July, and collected over 2000 responses from citizens and other interested parties. This was complemented by a further targeted consultation of a broad range of stakeholders.

**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). Following the evaluation of the FCM rules concluded in June 2022, the Commission launched a [public consultation](#) on 5 October 2022, which was open until January 2023, seeking views from all interested parties on the revision of the FCM legislation. The outcome of this, as well as other ongoing consultation activities, will feed into the ongoing impact assessment.

In September, the Commission adopted [Commission Regulation \(EU\) 2022/1616](#) on recycled plastic materials and articles intended to come into contact with foods. This regulation, together with the authorisations to be made under it, replaces the existing Regulation from 2008, and will facilitate the uptake of recycled plastics by the food packaging industry, which accounts for a major part of plastic packaging. The reinforced legal certainty over the rules applicable to plastic recycling represents a significant contribution to the Commission policy on the Circular Economy.

### **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*.

Following the Russian aggression, food security in Ukraine is of great concern, particularly due to the deliberate targeting of food storage locations by invading Russian forces. Additionally, countries that rely heavily on cereal imports from Ukraine and Russia (mainly in North Africa and the Middle East) are at heightened risk of food insecurity due to supply

chain disruptions. In response to this, the Commission published a [Communication on 23 March 2022](#) which outlined a number of measures being taken to safeguard global food security and support EU farmers and consumers that have been impacted by Russia's military aggression against Ukraine. The short-term and medium-term actions proposed aim at enhancing global food security and supporting farmers and consumers in the EU in light of rising food prices and input costs, such as energy and fertilisers.

DG SANTE also monitored closely the flow of goods subject to sanitary and phytosanitary requirements across the EU-Ukrainian border to avoid any delays and ensure, in close cooperation with the Member States, appropriate alternatives for border controls.

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 represents 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. In this context, following a request by the EU Council and the European Parliament, in June DG SANTE produced, in cooperation with DG AGRI, TRADE and ENV, [a report assessing the rationale and legal feasibility of applying EU health and environmental standards](#) (including animal welfare standards as well as processes and production methods) to imported agricultural and agri-food products, as well as identifying the concrete initiatives to ensure better consistency in their application, in conformity with WTO rules.

**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 2022, DG SANTE continued to promote food safety and quality standards, 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 promoted and supported relevant initiatives of the Food and Agriculture Organization (FAO), World Health Organization (WHO) and other UN agencies. In particular, DG SANTE promoted and defended EU interests in the Sanitary and Phytosanitary (SPS) Committee of the World Trade Organisation, where DG SANTE defended the EU position in the case of 41 Special Trade Concerns (STCs) raised against the EU.

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. It has also led the participation of the EU for the activities of the [Global Framework for the progressive control of Transboundary Animal Diseases \(GFTADs\)](#) in Europe, with the emphasis on African swine fever, lumpy skin disease and rabies. In 2022, DG SANTE coordinated the position of the EU MSs and EFTA countries for the adoption of the WOAH standards (Terrestrial Code, Aquatic Code and Biological Standards) at the annual WOAH World Assembly. In 2022 DG SANTE represented the EU in the Codex Alimentarius and advocated for due consideration of the One Health approach and sustainability aspects in the development of Codex standards. The EU advocated for protective Maximum Residue Levels (MRLs) for pesticides and protective Maximum Levels (MLs) for contaminants including aflatoxins in cereals, among other issues.

DG SANTE actively participated and contributed to the intersessional activities under the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety, and to the CBD Conference of the Parties (COP-15) and Cartagena Protocol meeting of the Parties (COP-MOP10). In particular the Global Biodiversity Framework agreed in Montreal now contains a target on biosafety, which was not the case for the previous biodiversity framework. In the International Plant Protection Convention (IPPC), DG SANTE was involved in the development of new standards for phytosanitary measures and revision of existing ones.

**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. SANTE will continue 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 2022, the technical negotiations on the SPS Chapter of an enhanced Partnership and Cooperation Agreement with Uzbekistan and Eastern and South African countries (ESA) countries were concluded. The FTA negotiations with New Zealand and Chile were concluded as well. On 14 December 2022, a Partnership and Cooperation Agreement with Thailand, including a SPS and a SFS chapter, was signed. In 2022 negotiations of the SFS Chapter advanced with Australia and were initiated with India and Indonesia.

Following five years of provisional application of CETA, Canadian and European businesses are reaping the benefits of CETA two-way trade having increased by over 30%. On SPS in particular, good co-operation in this area continued with a fruitful SPS Joint Management Committee (JMC) that took place in October 2022.

On the UK, DG SANTE worked to clarify and address issues in relation to the SPS import requirements for agri-food products from the EU and ensure the fulfilment of the country's commitments in the EU-UK Trade and Cooperation Agreement (TCA) to facilitate trade. Frequent technical contacts with the UK took place throughout the year, including a meeting of the Trade Specialised Committee which DG SANTE co-chairs.

DG SANTE and Japan worked closely to implement the Economic Partnership Agreement. Good progress was made with Vietnam regarding prelisting and regionalisation and with South Korea who recognised the principle of EU regionalisation being a major breakthrough. In addition, concrete progress on EU regionalisation was noted with Singapore.

In February 2022, the EU and the United States concluded negotiations allowing for bilateral trade in bivalve molluscs (e.g. mussels, clams, oysters and scallops) between a number of US States and EU Member States on the basis of mutually agreed equivalent SPS standards. This agreement allowed the parties to resume bilateral trade in these products after 11 years' interruption.

Meanwhile, DG SANTE and China worked closely under the MoU framework to prepare the first ever common working group on the application of zoning principles which took place in December 2022.

DG SANTE also worked on the successful negotiations for a number of enlargement-related dossiers.

The relations with the Eastern Partnership countries were of course strongly affected by Russia's invasion of Ukraine. In the SPS area DG SANTE initiated, in cooperation with the SPS authorities in the EU Member States, activities to facilitate the reception of Ukrainian refugees and their pets along with small quantities of food products into the EU and, if needed, on to other parts of the world. DG SANTE also contributed to the 'Solidarity Lanes-initiative' which sought to allow the exports of grains and cereals from Ukraine to other parts of the world via the territory of the EU Member States as an alternative to traditional routes via the Black Sea.

DG SANTE also contributed to preparing the reports for assessing whether certain countries (Ukraine, Moldova and Georgia) were ready to become EU candidate members. DG SANTE submitted the initial overviews on SPS (future Chapter 12) and Public health (future Chapter 28).

## General Objective 2: PROMOTING OUR EUROPEAN WAY OF LIFE

A graphic with a blue background on the left and a circular photo of a group of people, including children, on the right. The text 'EU solidarity with Ukraine' is in yellow and white. Below the photo, it says 'Open virtual meeting' and 'Supporting Ukraine, neighbouring EU Member States & Moldova' in a yellow box. At the bottom, it gives the date and time: 'Tuesday, 13 September 2022, 15:00 to 16:30 CEST' and includes the European Union flag.

**EU solidarity with Ukraine**

Open virtual meeting

**Supporting Ukraine, neighbouring EU Member States & Moldova**

Tuesday, 13 September 2022, 15:00 to 16:30 CEST



The Russian aggression against Ukraine impacted DG SANTE activities in the area of public health. The war brought devastating consequences for the physical and mental health of Ukrainian civilians. DG SANTE participated in [the Commission's efforts](#) to coordinate with other International Organisations, Non-Governmental Organisations (NGOs) 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 worked 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.

Under the EU4Health programme the European Commission also signed a contribution agreement with a final value of EUR 20.4 million (after being amended upward in July) with the International Federation of Red Cross and Red Crescent Societies to provide mental health and psychosocial support to persons fleeing Ukraine. This will support refugees who have experienced major mental health issues and psychological trauma with psychological first aid and assessment, as well as longer-term mental health and psychosocial support in their own language.

**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 and 2022. On 14 January 2022 the Commission adopted the [second annual work programme](#) with a budget of EUR 835 million. The third annual work programme for 2023 was adopted by the Commission on 21 November 2022 with a budget of EUR 735.8 million. Two amendments were adopted on 12 April 2022 and on 25 July 2022 to address the health consequences of the war in Ukraine. In 2022 DG SANTE started to develop 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. In July a historic step in deepening the partnership between the EU and Ukraine was taken with the signature of an [agreement for Ukraine's participation in the EU4Health programme](#). This will ensure that Ukraine can quickly access financial support to respond to the immediate needs of its healthcare system and also support long-term reconstruction.

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).

**International cooperation in the area of pharmaceuticals.** DG SANTE continued its bilateral relations with key strategic partners and its engagement as a Member in international regulatory convergence fora, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), promoting high level global standards of quality and safety and encouraging non-EU countries to apply them, as well as in the International Coalition of Medicines Regulatory Authorities (ICMRA). DG SANTE became an Associated Partner Organisation (Observer) in the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) with whom it also signed, together with the European Medicines Agency, a Working Arrangement on the exchange of non-public information. In addition, DG SANTE, together with the EMA and the competent authorities of the EEA countries, have interacted with the WHO to expeditiously proceed with the WHO evaluation to have the EU Regional Regulatory System in the area of pharmaceuticals recognised as a “WHO Listed Authority”. The active participation in these multilateral fora ensure a strong EU voice globally, in line with the Pharmaceutical Strategy for Europe in 2021.

Good progress was also made towards achieving the extension of scope of the EU’s [Mutual Recognition Agreements](#) with the US to include veterinary medicines..

In this area, ensuring smooth trade relations with the UK whilst preserving EU interests and implementing the Northern Ireland protocol is an additional challenge. The proposal put forward by the Commission at the end of 2021 was adopted in April, [ensuring the continued long-term supply of medicines](#) from Great Britain to Northern Ireland and addressing outstanding supply concerns in Cyprus, Ireland and Malta – markets that have historically been supplied through or by Great Britain.

DG SANTE manages a vast legislative acquis in the area of pharmaceuticals, on the basis of which several hundreds of delegated and implementing acts are adopted every year. Details of this important work are given in Annex 2.

### **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. In February 2022 on the occasion of World Cancer Day, SANTE launched a number of [new actions](#) which are tangible initiatives that will make a difference in the lives of cancer patients and their families, including: (1) the “PartnERship to Contrast HPV (PERCH)” - a Joint Action supporting Member States on Human papillomavirus (HPV) vaccination, (2) the Cancer Inequalities Registry and (3) the EU Network for Youth Cancer

Survivors. In addition, a communication campaign was run to address the backlog of cancer diagnosis and treatment resulting from the pandemic. Financed through the 2022 EU4Health work programme, a Network of Comprehensive Cancer Centres 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.

In September 2022 with the adoption of a [proposal to update the Council Recommendation on cancer screening](#) DG SANTE presented a new approach based on the latest science and technological developments to support Member States increasing the uptake of cancer screening. Focusing on detection of cancers at an early stage, the objective of the proposed recommendation is to increase the number of screenings realised, thus covering more target groups and more types of cancer. The [Council Recommendation](#), adopted in December 2022 by the Council, expands cancer screening to include lung, prostate and, under certain circumstances, gastric cancers.

Given the impact of COVID-19 on cancer screening, DG SANTE commissioned a testimonial video called “Marathon Man” which received more than 14 million views on social media and reached more than 6.9 million people via broadcast TV in France.

**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. As a first step towards its possible revision, DG SANTE launched an evaluation of 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. The [call for evidence](#) published in May attracted over 24 000 contributions. In parallel, DG SANTE started work to revise the Council Recommendation on smoke-free environments with the publication in June of a [call for evidence](#) which attracted some 200 contributions. In addition, in response to the significant increase in the volumes of heated tobacco products sold across the EU, DG SANTE prepared [a proposal to prohibit flavoured heated tobacco products](#) which was adopted by the Commission in June 2022.

**Non-Communicable Diseases.** DG SANTE strengthened its approach to supporting the Member States in achieving [target 3.4 of the United Nation Sustainable Development Goals](#), namely reducing the burden of non-communicable diseases. In June 2022 a [guidance document](#) was adopted as the first step of the initiative “**Healthier together – EU Non-Communicable Diseases**”, launched in December 2021 to help Member States and stakeholders address such major causes of mortality and morbidity as cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, as well as health determinants. SANTE’s work in this domain will complement and be coordinated with Europe’s Beating Cancer Plan.



[Healthier Together - the Commission's EU Non-Communicable Diseases \(NCD\) Initiative](#) particularly informed and supported DG SANTE's comprehensive vision of citizens' mental health, which also has a major role to play in improving citizens' health and well-being, while also reducing health inequalities. The Commission also rewarded community-based initiatives alleviating the mental health impact of COVID-19 via its [2021 EU Health award](#), for which the award ceremony was held in May 2022.

Following the announcement made by President von der Leyen in the State of the European Union speech in September 2022, DG SANTE is in the lead, and DG EMPL is associated, on a new initiative on mental health that will see the light in the second quarter of 2023. The initiative will take the form of a Communication intended to promote a comprehensive, prevention-oriented approach to mental health as a public health issue and to mainstream mental health into EU policies. A number of actions have been put in motion in 2022 to collect the views of citizens, Member States and stakeholders, including a Call for Evidence and targeted consultations.

**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 planned revisions of the general EU pharmaceutical legislation and the EU legislation on medicines for children and rare diseases, for which Commission proposals are planned for April 2023. Two accompanying impact assessments looked at possible options to foster innovation including in areas of unmet medical need

(including antimicrobials) and to enhance security of supply while adapting to new scientific and technological developments and reducing regulatory burden. The revision of the pharmaceutical legislation will deliver on the Commission's political priorities and the twofold objective of ensuring Europe has the supply of affordable medicines to meet its needs whilst helping the European pharmaceutical industry remain an innovator and world leader. The revision will also address a number of specific shortcomings that were detected during the evaluations on the [legislation on medicines for children and rare diseases](#) and on

the general pharmaceutical framework, as well as the lessons learnt from the COVID pandemic.

To implement the Pharmaceutical Strategy, the Commission also stepped-up co-operation with Member States on the affordability and cost-effectiveness of medicines, steering cooperation between national pricing and reimbursement authorities and healthcare payers. Best-practice exchanges took place on a broad spectrum of topics related to access, affordability and price-cost effectiveness. The Commission also published in October 2022 a [Staff Working Document](#) summarising the findings of the 2021 Structured Dialogue on security of supply and mapping areas of priority activities at EU level to inform further actions to improve the security of supply and the availability of critical medicines, active pharmaceutical ingredients and raw materials.

Of the 103 new medicines authorised for human use in 2022, 53 included a new active substance, and 24 were authorised for treatment of rare diseases (of which 4 are advanced therapy medicines). During the course of 2022, the Commission adopted 1056 decisions amending marketing authorisations and 182 new designations for orphan medicines. With regard to the result indicator '2.2.A: Access to centrally authorised medicines for unmet needs', 27 new authorisations were granted (see Annex 2). A [proposal](#) for the revision of the fee system of the European Medicines Agency was adopted in December 2022, which aims to bring the fee system into line with existing legislation and also provide more flexibility and simplicity in the future, while ensuring the fees charged are clearly cost-based.

**Implementation of the Clinical Trials Regulation.** On 31 January 2022, [the EU portal and EU database for clinical trials](#) of medicinal products for human use went live. The portal and database are major components of the Clinical Trials Information System (CTIS), established by the [Clinical Trials Regulation](#) of 2014 and managed by EMA. DG SANTE continues to work with EMA and the Member States to implement the Regulation which aims to harmonise the registration and supervision processes for clinical trials throughout the EU. Union controls (audits) under the regulation were launched in Member States during the year.

**Health Technology Assessment.** Health Technology Assessment (HTA) 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 safe and effective 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 2022 focused on establishing the governance bodies of the new EU HTA system. SANTE successfully organised a public stakeholder conference in June 2022 on the new system, and a dedicated IT platform and an IT user group is being established, with 13 Member States having joined to date.

**Medical Devices and In Vitro 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, notably insufficient capacity of notified bodies and lack of manufacturer preparedness. As regards IVDs, on 25 January 2022, the European Parliament and the Council adopted [Regulation \(EU\) 2022/112](#) allowing for a progressive roll-out of some provisions of the IVDR, introducing a staggered approach to transition

periods depending on the risk class of the IVDs. To further the implementation of the IVDR, in July DG SANTE also issued a call for applications to Member States for EU reference laboratories (EURLs), which will play a key role in ensuring the safety and compliance of IVDs with the Regulation.

The issue of capacity and preparedness has remained the main focus in 2022. DG SANTE facilitated interactions among Member States, notified bodies and stakeholders, notably in the framework of the Medical Device Coordination Group (MDCG), to mitigate risk of shortages. An action plan including 19 mitigating measures was endorsed by the [MDCG](#) in August 2022. As these actions were not considered sufficient to address the important availability issue, DG SANTE worked intensively towards the end of the year on a legislative proposal to extend the transitional deadlines in a staggered approach and under certain conditions. The proposal was adopted on 6 January 2023 and sent to the co-legislators.

Twelve new notified bodies assessing the conformity of devices have been designated for medical devices and 2 for *in vitro* diagnostics in 2022, bringing the total numbers to 36 and 8 respectively. The Commission has adopted eleven new implementing and delegated acts in 2022 and over 30 technical guidance documents have been endorsed by the MDCG to provide guidance on the implementation of the Regulations. To provide additional targeted support a number of actions co-funded by the EU4Health Programme have also been put in place.

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

As the acute phase of Covid-19 began to recede, while other diseases continued to spread (mpox, ebola, hepatitis...), DG SANTE continued to be at the core of the Commission's [coordination of the EU response to the pandemic](#), as well as working to reinforce resilience to and preparedness for serious threats to health.

On 2 September the [Communication on an EU response to Covid-19: preparing for autumn and winter 2023](#) was adopted. This Communication, building on the [set of actions proposed earlier in April](#), urged Member States to put the necessary integrated strategies and measures in place to help avoid a surge of COVID-19 in the autumn and winter, and to establish the necessary structures to respond to future outbreaks in a sustained manner.

Attention increased in 2022 on the consequences of the pandemic, including as regards “**long COVID**” syndrome. On 13 December, following request from the Commission, the Expert Panel on effective ways of investing in health published an opinion on the impact of long COVID on health systems and the Commission hosted an online conference with over 800 participants to highlight the latest news and developments on long COVID in the EU and the United States of America.



On 22-23 November 2022, the conference “**COVID-19 lessons learned and looking ahead to ensure a stronger EU Health Security Framework**” was organized in Luxembourg in collaboration with the Ministry of Health of Luxembourg. Over 500 policy-makers, public health experts, healthcare professionals and representatives of different governmental and non-governmental organisations met to shape EU policy going forward and to build a stronger EU health security framework. The conference took stock of the lessons to be learned in public health since the beginning of the pandemic and looked at

key initiatives resulting from these, such as the new Regulation on cross-border threats to health.

**Preparedness and Response.** The European Health Security Framework is the Commission's key response to the COVID-19 pandemic and encompasses four key initiatives.

The adoption of the Health Union package i.e. the [Regulation on serious cross-border threats to health](#) and the [Regulations that strengthen the mandate of the European Centre for Disease Prevention and Control \(ECDC\)](#) and of [the European Medicines Agency \(EMA\)](#), was completed in 2022.

The Regulation on serious cross-border threats to health, which entered into force on 26 December 2022, is the umbrella framework for all work on prevention, preparedness and response. It aims to ensure a stronger and more comprehensive legal framework for the Union to better prevent, prepare and respond to serious cross-border threats to health and other public health emergencies. With its revised mandate, the ECDC will be able to issue recommendations to Member States regarding preparedness and response, host a new network of EU reference laboratories and establish an EU Health Task Force for crisis preparedness and rapid public health interventions in case of a major outbreak.

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. In addition, Council adopted an Emergency Framework Regulation proposed by the Commission to provide extra powers to the European Health Emergency Preparedness and Response Authority (HERA).

The [Joint Procurement Agreement for medical countermeasures](#) has been paramount in fighting the COVID-19 pandemic. An assessment of the JPA mechanism is currently ongoing to look at how joint procurement has worked before and during the COVID-19 pandemic.



**Vaccination.** Vaccination remained central to a sustainable exit from the COVID-19 pandemic throughout 2022.

In 2022, regulatory actions and policy-related activities to support the development, authorisation and close monitoring of COVID-19 vaccines and therapeutics continued

to be a priority for DG SANTE. In addition to the five COVID vaccines already authorised, the Commission authorised two new vaccines: in June, [a vaccine](#) which contains inactivated whole particles of the original strain of SARS-CoV-2; and in November, another one for use as a booster. Moreover, in September, the Commission authorised the first two COVID-19 booster vaccines adapted to the Omicron B.1 variant, followed later in the year by the adapted vaccines targeting the Omicron subvariants BA.4 and BA.5. Finally, in August, a protein Covid vaccine was [included in the joint procurement programme](#). Effective public communication, including by addressing mis/disinformation, continued to be an essential element to increase the uptake of new vaccines and booster doses.

Meanwhile, people fleeing Ukraine were offered healthcare in the EU through the Temporary Protection Directive, which often included vaccination against vaccine-preventable diseases, including COVID-19.

In order to ensure that vaccines and other pandemic response tools are available to all countries, DG SANTE also continued to contribute to the work of the Access to [COVID-19 Tools \(ACT\) Accelerator](#), a partnership launched by WHO and other parties to support global efforts to develop tools to fight diseases.

In parallel with the work on COVID-19 vaccination, DG SANTE continued work on vaccination in line with the Council Recommendation on strengthened cooperation against vaccine-preventable diseases from 2018. The actions planned in the roadmap to increase vaccination coverage rates were practically all completed by December 2022. The European Joint Action on vaccination, whose achievements fed into the roadmap, ended in March 2022, delivering a wealth of new resources.

A [“United In Protection”](#) awareness raising campaign on the benefits of vaccination across the life course was launched at the end of 2022 and will run until mid-2023, with dedicated sections on COVID-19, seasonal influenza and HPV. In the first month, there were already around 200,000 engagements with the campaign webpage.



**Antimicrobial Resistance (AMR).** With 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 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, Codex, G7 and G20 level, in the areas of antimicrobial resistance and for the prevention of future pandemics, and continued the strong cooperation with the U.S., Canada, Norway and UK at the Transatlantic Taskforce on Antimicrobial Resistance – TATFAR. In addition, under the partnership instrument, AMR-related activities are being initiated in collaboration with the South Asian countries. SANTE carried out a number of One Health audits in Member States on rabies (one audit) and avian influenza (four audits).

DG SANTE pursued the implementation of the 2017 AMR action plan laying out over 70 actions to fight AMR. In November, DG SANTE published a [report reviewing Member States’ One Health antimicrobial resistance \(AMR\) national action plans \(NAPs\)](#). The report found that NAPs are in place in all Member States, with most based on a One Health approach, at least to some extent, though the NAPs vary considerably in content and detail, and concluded that many Member States should work more on the One Health dimension, particularly regarding the environment, which is often missing or not well developed. In this perspective, DG SANTE continued work to prepare a Council Recommendation for strengthened actions against AMR aiming at setting concrete objectives and activities to strengthen Member States’ action against AMR, mainly in the area of public health.

The review was accompanied by a [Eurobarometer survey](#), which revealed widespread public misunderstanding of the way in which antibiotics act. SANTE also released [an opinion by the Expert Panel](#) on effective ways of investing in health to manage AMR across the health system.

The EU AMR One-Health Network, chaired by DG SANTE, continued to meet in 2022, and in February, a temporary subgroup composed of the 27 Member States’ representatives was set-up and tasked to formulate suggestions for new AMR actions. [The subgroup’s report](#) was published in September, providing recommendations and concrete suggestions for priority actions.

AMR is also a flagship initiative of the Pharmaceutical Strategy for Europe. Within the revision of the pharmaceutical legislation, DG SANTE assessed several options for incentives for innovative antimicrobials and measures on the prudent use that could be included in the pharmaceutical legislation.

**Engagement at international level.** In 2022 DG SANTE together with DG INTPA developed a new EU global health strategy which was adopted by the Commission on 30 November to respond to the challenges that have emerged since the 2010 Communication on the [EU role in global health](#), including the COVID-19 pandemic, the increasing effect of climate change

and biodiversity loss, and the evolution of infectious and non-communicable diseases. The Strategy sets out a new vision to regain the lost ground as to the 2030 Sustainable Development Goals and reinforce our combat against health threats by expanding partnerships and strengthening the multilateral system with the WHO at its core.

DG SANTE continued to stand alongside the United Nations, the World Health Organization, G7 and G20 to ensure coordinated global action. In the discussion on improving the global health security architecture, SANTE particularly focused on the discussions to strengthen the World Health Organization to enable it to fulfil its mandate and meet the expectations of the global community. In particular, DG SANTE advocated for more sustainable financing in line with the decisions of the 75th World Health Assembly as well as for a WHO reform strengthening its governance, efficiency and accountability.

In March 2022, the Council adopted a decision to authorise the opening of negotiations for an [international agreement on pandemic prevention, preparedness and response](#). SANTE led the European Union's work in this area and participated actively throughout the year in the intergovernmental negotiating body that is tasked with drafting and negotiating this instrument, which is scheduled to be presented to the World Health Assembly in 2024 in view of its possible adoption. The Commission, including SANTE, was also a key player in the establishment in September 2002 of the [Pandemic Fund](#) hosted by the World Bank, which provides critical investments to strengthen pandemic prevention, preparedness, and response capacities at national, regional, and global levels, with a focus on low- and middle-income countries. Another important step was the adoption in May by the 75th World Health Assembly of an amendment to the International Health Regulations shortening the period for rejecting amendments from 18 to 10 months and the period before such amendments come into force from 24 to 12 months.

#### **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 the 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 expansion of the MyHealth@EU infrastructure for the cross-border exchange of patients' health data continued with the support from EU funding, including EU4Health. Two new Member States joined the infrastructure in 2022 bringing the total number of connected Member States to 11, and additional services were launched by those already connected.

Preparations for the implementation of support for further health data categories were launched in the framework of the eHealth Network.

In October 2022 the Commission launched the [pilot of HealthData@EU](#) in the area of secondary use of health data. The HealthData@EU pilot supported by the EU4Health programme brings together 16 partners (including Member States authorities, EMA and ECDC), and has a planned duration of 24 months.

In February the Commission proposed to [extend the EU Digital COVID Certificate Regulation](#) by a year, until 30 June 2023, as the COVID-19 virus continued to be prevalent in Europe. This extension approved by the co-legislators ensured that travellers can continue using their EU Digital COVID Certificate when travelling in the EU. In 2022 discussions continued with other concerned DGs on possible future uses of the certificate after June 2023. In addition, SANTE participated in preparing equivalence decisions to connect third countries and territories to the system, bringing the total number of connected countries to 76.

**Health systems.** DG SANTE has continued to work in collaboration with SG-RECOVER, ECFIN and EMPL to assess health related investments and reforms proposed in the Recovery and Resilience Plans and monitor their implementation. All of the 27 national plans adopted include measures related to health. In addition, DG SANTE contributed to the 2022 European Semester, including through the delivery of thematic Annex on Health and Health Systems in all 27 [Country Reports](#). Moreover, [Country Specific Recommendations](#) addressing healthcare reforms were issued for 8 Member States. DG SANTE has continued to generate country-specific and cross-country knowledge on health systems, in particular through the launch of the 4th cycle of the “State of Health in the EU”, a project in collaboration with the OECD and the European Observatory on Health Systems and Policies. As part of the project, on 5 December DG SANTE co-published the 2022 edition of [Health at a Glance: Europe](#). The publication focuses on the impact of the COVID-19 pandemic on the health of children and young people, as well as on the pandemic’s impact on health services for non-COVID patients.

**Health Workforce.** Adequate staffing levels have become a very urgent issue during the COVID-19 pandemic, adding to existing structural challenges in health care delivery. An [agreement for a joint action on health workforce planning and forecasting](#) was signed under EU4Health in 2022, with its kick-off planned for the first quarter of 2023. Further, the launch event of the [Pact for Skills large-scale partnership on re- and upskilling of the health workforce](#), in collaboration with DGs GROW and EMPL, took place on 13 December 2022. Calls for proposals for training of health workforce including digital skills were launched in 2022 under the EU4health programme.

**Substances of human origin (SoHO).** In July the Commission adopted a [proposal for a new Regulation](#) with a view to further increasing the safety and quality of substances of human origin used in the EU. With this proposal, citizens will be safer when donating or receiving vital substances of human origin (SoHO), from blood to tissues and cells, but also breast milk or microbiota. More specifically, the new Regulation will aim to facilitate cross-border circulation of these critical health products. It will reinforce solidarity between public health authorities, ensuring that the sector can manage the supply of critical substances and promote innovation while guaranteeing the same high standards of quality and safety for all citizens.

**Patients' right to cross-border healthcare.** EU citizens have the right to access healthcare in any EU country and to be reimbursed for care abroad. In 2022 DG SANTE finalised the [evaluation](#) of the provisions of the Cross-border healthcare Directive that govern patients' rights in this respect and published a report in May which concluded that the Directive has been moderately effective in delivering its objectives to facilitate access to safe and high-quality healthcare in another EU country. The evaluation identified challenges in the implementation of EU rules concerning in particular (a) citizens' and healthcare professionals' lack of awareness of the opportunities created by the Directive, (b) challenges in accessing information on care options abroad and (c) obstacles stemming from prior authorization procedures and price transparency.

**European Reference Networks.** The 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. An Independent Body has been appointed by DG SANTE to conduct the evaluation of the first five years of operation of the 24 networks and their members. The results of the evaluation will be used for the next phase of development of the Networks, and a series of EU grants will be launched in 2023 to support this.

## **2. MODERN AND EFFICIENT ADMINISTRATION AND INTERNAL CONTROL**

### **2.1 Financial management and internal control**

Assurance is provided on the basis of an objective examination of evidence of the effectiveness of risk management, control and governance processes.

This examination is carried out by management, who monitors the functioning of the internal control systems on a continuous basis, and by 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 DG SANTE.

This section covers the control results and other relevant elements that support management's assurance. It is structured into 2.1.1 Control results, 2.1.2 Audit observations and recommendations, 2.1.3 Effectiveness of internal control systems, and resulting in 2.1.4 Conclusions on the assurance.

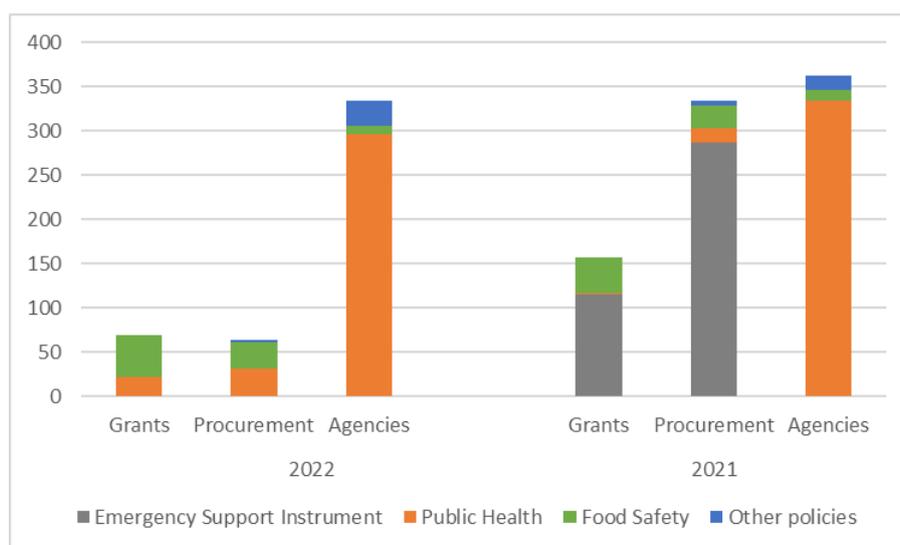
## 2.1.1 Control results

This section reports and assesses the elements identified by management which support the assurance on the achievement of the internal control objectives (ICO) <sup>(2)</sup>. The DG's assurance building and materiality criteria are outlined in annual activity report annex 5, while annex 6 outlines the main risks, the control processes to mitigate them, and the indicators used to measure the performance of the relevant control systems.

In line with the specific reporting requirements stemming from the Financial Regulation<sup>3</sup>, in 2022, DG SANTE has the following case to report: with regard to veterinary and plant emergency measures, a derogation from the principle of non-retroactivity of grants pursuant to Article 193.2 Financial Regulation is set out in the Single Market Programme Regulation<sup>4</sup> (Article 3.5).

No cases are to be reported under the following provisions of the Financial Regulation: Article 92.3 on 'confirmation of instructions'; Article 125.3 on 'financing not linked to costs', Article 130.4 on Financial Framework Partnership Agreements exceeding the four-year duration; Article 181.6 on flat rates exceeding 7% for indirect costs.

**Figure 2.1 DG SANTE's 2022 budget implementation (EUR 467.2 million payments made) in comparison to 2021**



<sup>(2)</sup> The five internal control objectives are 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).

<sup>3</sup> Regulation (EU, Euratom) 2018/1046 on the financial rules applicable to the general budget of the Union, repealing Regulation (EU, Euratom) No 966/2012 (2012 Financial Regulation):

<sup>4</sup> Regulation (EU) 2021/690 of 28 April 2021 on the Single Market Programme (SMP)

The objectives, indicators and assessments in this section cover all expenditure and other significant non-expenditure items<sup>5</sup>. DG SANTE managed financial operations under two policy areas, Health and Food Safety. 2022 was the second year of implementing the new Multi-annual Financial Framework (MFF) covering the 7-year period from 2021 to 2027<sup>6</sup>. DG SANTE's budget for 2022 was no longer dominated by the Emergency Support Instrument (ESI)<sup>7</sup> to fight the COVID-19 pandemic which required exceptional budgetary resources in 2020 and 2021 to support the Member States. The ESI expired in January 2022 and was not reactivated.

Since 2021, the EU4Health Programme<sup>8</sup> is the Union's response to the current public health situation and will make a significant contribution to the post-COVID-19 recovery. The EU4Health Programme has an envelope of EUR 5.3 billion (2021-2027). In 2022, DG SANTE managed a budget of EUR 580.2 million in commitment credits and EUR 152 million in payments, mainly for the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe and the implementation of Union health legislation in general. DG SANTE transferred about 80% of the budget implementation tasks to the Health and Digital Executive Agency (HaDEA).

DG SANTE's spending in the policy area Food Safety remained relatively stable over the last few years. The Single Market Programme<sup>9</sup> (SMP) includes a dedicated food chain strand of EUR 1.7 billion (2021-2027). DG SANTE's budget in 2022 amounted to EUR 312 million commitments and EUR 211 million payments, implemented to a large part (68%) by HaDEA.

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<sup>5</sup> 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.

<sup>6</sup> Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020.

<sup>7</sup> 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.

<sup>8</sup> Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme; C(2022) 317 of 14 January 2022 – 2022 work programme of EU4Health, last amended on 25 July 2022 C(2022) 5436.

<sup>9</sup> Regulation (EU) 2021/690 of 28 April 2021 on the Single Market Programme (SMP)

**Table 2.1 Overview table of DG SANTE's budget implementation - payments made in 2022<sup>10</sup>**

Risk type / Activities	Grants	Procurements	Budget transfer to HaDEA	Subsidy payments to agencies	Total	
	M€	M€		M€	M€	%
Food and Feed	47,9	25,4	137,7		<b>211,0</b>	30,0%
Public Health	21,4	31,9	98,7		<b>152,0</b>	21,6%
Emergency Support Instrument		0,1			<b>0,1</b>	0,0%
Building expenditure, etc, Ireland		2,8			<b>2,8</b>	0,4%
Other policies*		4,1		28,1	<b>32,2</b>	4,6%
HaDEA/CHAFFEA				13,9	<b>13,9</b>	2,0%
ECDC				99,9	<b>99,9</b>	14,2%
EFSA				134,7	<b>134,7</b>	19,1%
EMA				49,7	<b>49,7</b>	7,1%
ECHA-biocides				7,3	<b>7,3</b>	1,0%
<b>Total (including HaDEA)</b>	<b>69,3</b>	<b>64,3</b>	<b>236,4</b>	<b>333,6</b>	<b>703,6</b>	<b>100%</b>
<b>Total (excluding HaDEA as in Annex 3)</b>	<b>69,3</b>	<b>64,2</b>		<b>333,6</b>	<b>467,1</b>	
<b>EC balance sheet category</b>						<b>M€</b>
<i>Intangible Assets - internally generated IT software</i>						13,3
<i>Assets - inventories of vaccines and antigen stocks for animal diseases</i>						13,9

ad \*: Co-delegations received from other DGs, incl M€28,1 of administrative credits for HaDEA

### 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 strand<sup>11</sup> 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".
- About 65% of the payment budget for the Food Chain strand in 2022 was implemented by HaDEA, mainly 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. Around 35% of the payment budget was implemented by DG SANTE firstly, for veterinary and plant health emergency measures (EUR 43 million) which are implemented through grants to Member States and third countries based mainly on the co-financing of eligible costs. A large part of the payments for procurement (EUR 17 million) were made for IT services, mostly using framework contracts of DG DIGIT. DG SANTE also procured vaccines/antigens for the EU animal health vaccine banks for which it paid in 2022 a

<sup>10</sup> Payments made on the basis of the final available credits taking into account EFTA credits, budget amendments and/or budget transfers without credits co-delegated to other DGs.

<sup>11</sup> 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

total of EUR 2.2 million, mainly related to two procurement contracts that were transferred from HaDEA back to DG SANTE. Payment credits were consumed to 96%. The main features of the corresponding internal control systems are listed in Annex 6.1.1; the control results are explained in Annex 7.1.1.1.

#### **EU4Health Programme – 2022 work programme**

- Under the general objective 2 “Promoting our European way of life”, the EU4Health Programme<sup>12</sup> 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 2022 work programme was amended on 25 July 2022<sup>13</sup> to contribute to the response to Russia’s aggression on Ukraine. A contribution agreement for a total value of EUR 20.4 million was signed with the International Federation of the Red Cross and Red Crescent Societies to support mental health and psychosocial assistance for displaced people coming from Ukraine (pre-financing payments of EUR 13.4 million were made in 2022).

About 65% of the payment budget for the Health Programme in 2022 was implemented by HaDEA. DG SANTE implemented the remaining 35% through contribution agreements with international organisations under indirect management (EUR 22.7 million mostly in pre-financing payments) and public procurement procedures, for example, through concluding framework contracts for IT services (EUR 13.8 million) and for administrative arrangements with JRC (EUR 8.4 million). The total of payment credits was consumed to 97%. The relevant internal control systems and results are described in Annexes 6.2 and 7.1.1.

#### **Emergency Support Instrument<sup>14</sup> (ESI) to address the COVID-19 pandemic**

- The ESI expired on 31 January 2022 and was not reactivated. In 2022, DG SANTE made three small payments for IT services related to eHealth Digital Service Infrastructure (eHDSI).

Pre-financing payments that were made in 2020 and 2021 for Advance Purchase Agreements for COVID-19 vaccines<sup>15</sup> were cleared in 2022 based on the value of

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

<sup>13</sup> C(2022) 5436: 2022 work programme of EU4Health as last amended on 25 July 2022

<sup>14</sup> 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.

<sup>15</sup> In 2020 and 2021, the Commission signed eight Advance Purchase Agreements (APA) for COVID-19 vaccines to secure over 4 billion doses of COVID-19 vaccines. Seven of the eight APAs led to vaccines that received marketing authorisation. One agreement was terminated as the contractor informed the Commission that they would not be in a position to obtain marketing authorisation by the set deadline of late 2021.

vaccine doses delivered to the Member States. No more payments will be made and no pre-financing remains open after 31 December 2022.

### **Other policy areas**

- An amount of EUR 28.1 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 2022. The internal control system is described in Annex 6.2.1 (agencies).
- DGs AGRI and CNECT co-delegated about EUR 2.6 million on operational budget lines for IT services, mainly related to the IT systems TRACES and EUDAMED. DG NEAR co-delegated EUR 1.5 million for the multi-country action plan (2021-2022) in favour of the Western Balkans. Commitment and payment credits were fully consumed. The internal control systems are described in Annex 6.1.2 (procurement).

### **Agencies**

- DG SANTE paid subsidies to finance – partially or in full – the operating budgets of the executive agency HaDEA and four EU decentralised agencies (for detailed figures and explanations see Annexes 6.2.2 and 7.1.1.3).

### **Building expenditure for Grange, Ireland**

- EUR 2.8 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 53% in 2022, and as payments can still be made in 2023, the credits are expected to be fully used. The relevant internal control systems are described in Annexes 6.1.2 and 7.1.1.2 (procurement).

### **Balance sheet:**

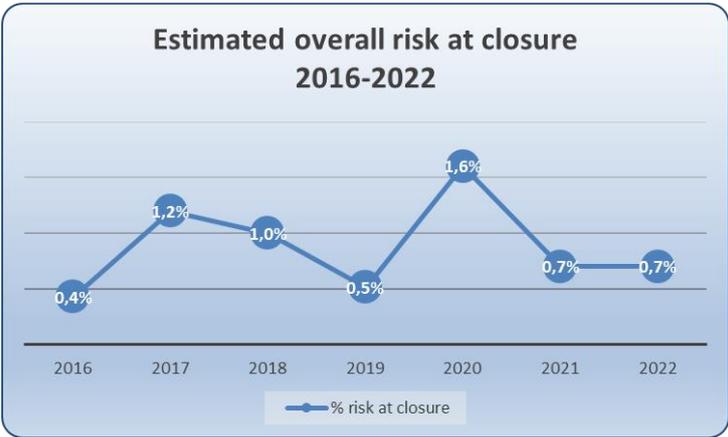
- DG SANTE identifies internally generated intangible assets (IT software for eHealth and EUDAMED (European database for medical devices) of a total value of EUR 13.3 million (see section 2.1.1c below).
- In its balance sheet, DG SANTE identified current assets (inventories) of a total value of EUR 13.9 million at 31 December 2022. The assets pertain to antigen stocks for food and mouth disease in order to carry out emergency vaccination (see section 2.1.1c below). No other vaccines or antigens were in stock at the end of 2022.

## **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.

**Figure 2.2**



The coverage of the Internal Control Objectives and their related main indicators are described in more detail in Annexes 6.1 and 7.1. One of the key performance indicators of the control objective "legality and regularity" is DG SANTE's estimated overall risk at closure based on the error rate found during DG SANTE's on-the spot controls. 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).

DG SANTE's portfolio consists of several segments with different error rates as follows: during ex-post controls on grants for Member States' animal disease eradication programmes in the Food Safety policy, in previous years (2016 to 2021), the error rate was consistently below 2%. This was achieved thanks to DG SANTE's mitigating actions, such as the clarifications of eligible costs in the legislation, the introduction of unit-costs and/or cost-ceilings in 2014 and the performance of the related control systems.

In 2022, however, DG SANTE detected an error rate of 5.2% in a relatively small sample<sup>16</sup> of eradication programmes of 2018 and 2019. Overpayments of a total of EUR 0.4 million were detected in three cost claims mainly due to misunderstandings of the eligibility rules in one cost category. The errors cannot be extrapolated to DG SANTE's 2022 expenditure as this type of grant was transferred to HaDEA in 2021 to the effect that DG SANTE made no more payments for eradication programmes in 2022. Moreover, under the Multiannual Financial Framework (2021 to 2027), the eligibility rules for eradication programmes have changed with the introduction of lump-sums covering – for the first time – also the cost category in which the errors were found. The only grants in the Food Safety policy area that remain with DG SANTE are related to Member State's veterinary and phytosanitary emergency measures. As they are subject to extensive ex-ante controls, including on-the-spot audits, but no ex-post audit has been finalised in 2022, the error rate is estimated conservatively at 2%.

In accordance with the control strategy, no ex-post audits took place on the procurement contracts in either policy area as these were mostly fixed price contracts. For the purpose of estimating the overall risk at closure, a worst-case error rate of just under 2% is set as a default for procurement expenditure and an error rate of 0.5% is set for low-risk types of

<sup>16</sup> The finalised audits in 2022 represent a sample size covering only a third of the average sample size of the last three years (2019 to 2021).

expenditure (such as subsidy payments to agencies or lump-sum grants); the future corrections are prudently estimated at 0%.

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.

For the 2022 reporting year, the executive agency HaDEA has itself reported reasonable assurance 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.

For all five EU decentralised agencies (EFSA, EMA, ECDC, CPVO, and ECHA for its biocides activities) for which DG SANTE was responsible in 2022, the Court of Auditors gave a positive declaration of assurance for the year 2021. The 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. Consequently, 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.

In addition, DG SANTE has in place an effective mechanism for correcting errors, through ex-ante and ex-post controls, resulting in preventive and corrective measures, respectively. Please see the table below for details:

**Table 2.2: Corrective measures**

	Preventive Measures M€	Corrective measures M€
DG SANTE total	2,1	0,8

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

**Table 2.3 : Estimated risk at payment and at closure (amounts in EUR million)**

DG SANTE	Payments made	Relevant expenditure	Estimated risk (error rate %) at payment		Estimated future corrections and deductions		Estimated risk (error rate %) at closure	
	MEUR	MEUR	MEUR	%	MEUR	%	MEUR	%
Food Safety (Grants to Member States)	43,33	70,17	1,40	2,00%	0,52	0,74%	0,89	1,26%
Contribution agreements and other grants with International organisations (Mainly indirect management)	25,39	1,20	0,02	2,00%	-	0,00%	0,02	2,00%
Procurement in Health and Food Safety	64,84	64,69	1,29	2,00%	-	0,00%	1,29	2,00%
Emergency Support Instrument (lump sums and deliveries)	-	549,37	2,75	0,50%	-	0,00%	2,75	0,50%
Subsidies to EU decentralised agencies	291,60	307,97	1,54	0,50%	-	0,00%	1,54	0,50%
<b>A: Total without contribution to the Executive Agency's operating budget</b>	<b>425,16</b>	<b>993,40</b>	<b>7,01</b>	<b>0,71%</b>	<b>0,52</b>	<b>0,05%</b>	<b>6,49</b>	<b>0,65%</b>
<b>B: Total DG's contribution to HaDEA's operating budget</b>	<b>42,01</b>	<b>24,57</b>	<b>0,12</b>	<b>0,50%</b>	<b>-</b>	<b>0,00%</b>	<b>0,12</b>	<b>0,50%</b>
<b>Total DG A+B</b>	<b>467,18</b>	<b>1.017,97</b>	<b>7,13</b>	<b>0,70%</b>	<b>0,52</b>	<b>0,00</b>	<b>6,61</b>	<b>0,65%</b>

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

The estimated overall risk at payment for 2022 expenditure is the AOD's best conservative estimate of the amount of relevant expenditure during the year, not in conformity with the contractual and regulatory provisions applicable at the time the payment was made. This expenditure will subsequently be subject to ex-post controls and a proportion of the underlying errors may be detected and corrected in subsequent years. This amount corresponds to the conservatively estimated future corrections for 2022 expenditure.

The difference between those two amounts results in the estimated overall risk at closure <sup>(17)</sup> of EUR 6.6 million, representing 0,7% of the DG's total relevant expenditure for 2022. The risk at closure of 0,7% remains unchanged in comparison to 2021 given that the risk structure of DG SANTE's expenditure in 2022 is similar to 2021.

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.

### **b) Fraud prevention, detection and correction**

DG SANTE has developed and implemented its own anti-fraud strategy since 2013, on the basis of the methodology provided by OLAF. It is updated every three years. It was last updated on 8 November 2021 together with an action plan. Its implementation is being monitored and reported to the management twice a year.

<sup>(17)</sup> This is the AOD's best, conservative estimation of the expenditure authorised during the year that would remain not in conformity of applicable regulatory and contractual provisions by the end of implementation of the programme.

Important new actions, such as awareness raising on “How to work with lobbyists and stakeholders in policymaking” and an information session on ethics for all staff in DG SANTE, were implemented in 2022 as planned. However, due to a re-prioritisation during the ongoing COVID-19 pandemic, only about 75% of all actions were completed since some of the awareness raising campaigns could not take place as planned. They will resume in 2023.

DG SANTE contributed to the Commission anti-fraud strategy (CAFS) and currently cooperates with OLAF on the revision of the CAFS Action Plan, especially by further developing the existing channels of cooperation with OLAF, and through DG SANTE’s active participation in the Fraud Prevention and Detection Network and the sub-group of correspondents for EPPO (European Public Prosecution Office). During the summer 2022, DG SANTE participated in OLAF’s actions feeding into the evaluation of the 2019 CAFS Action Plan and communicated to OLAF the identified fraud risks for the Commission’s corporate fraud risk exercise. In September 2022, the Director General of DG SANTE appointed a new central contact point for OLAF responsible for the co-operation with OLAF in respect of both investigative and fraud prevention matters.

In 2022, DG SANTE became aware of one allegation of fraud which is under investigation by OLAF.

All follow-up actions to implement OLAF recommendations from previous OLAF cases were closed since 2013; no new recommendation has been issued since.

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

### **c) Other control objectives: safeguarding of assets and information, reliability of reporting**

In its balance sheet, DG SANTE identified internally generated intangible assets of a total value of EUR 13.3 million at 31 December 2022. The assets pertain to IT software developed by DG SANTE for eHealth (EUR 4.3 million) and EUDAMED (EUR 9.0 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 13.9 million at 31 December 2022. The assets pertain to antigen stocks for food and mouth disease in order to carry out emergency vaccination. No other vaccines or antigens were in stock at the end of 2022.

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.

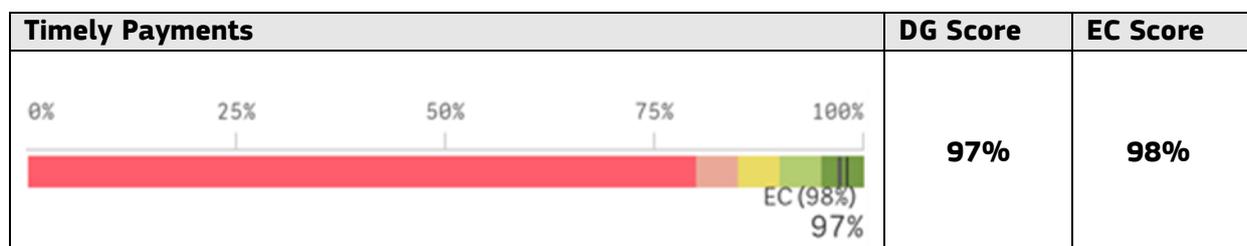
In conclusion, DG SANTE considers the current control arrangements for accounting and financial reporting to be sufficient. They work in practice as intended. Proper safeguarding of the DG SANTE inventories was ensured throughout the year as stated in the reports received from the contractors.

## 2. Efficiency of controls

The main efficiency indicators monitored in 2022 focussed on the timeliness of budget implementation. Due to the late agreement on the new Multiannual Financial Framework (2021-2027) in December 2020<sup>18</sup>, 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 budget had repercussions on the implementation of the 2022 budget, as priority had to be given to actions under the 2021 work programme. Despite the late start, DG SANTE achieved a 100% implementation of the 2022 must-use commitment credits.

Thanks to proper planning and as a result of the return of payment credits during the global transfer<sup>19</sup> and year-end transfer, DG SANTE managed to consume 99% of the 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 2022, DG SANTE's indicator of timely payments (97% of amounts paid on time) is slightly lower than the Commission average of 98% (for more indicators and explanations see Annexes 4 and 7.2) Efficiency indicators such as "time-to-inform" and "time-to-grant" (Art 194.2 of the Financial Regulation) were not applicable in 2022 to DG SANTE's grant agreements in 2022.



In its 2022 Management Plan, DG SANTE identified two initiatives to improve economy and realise efficiency gains in financial management. The first initiative refers to the revision of the use of unit costs and lump-sums in the SMP, following the revision of the financing system for EU support to Member States in the framework of veterinary programmes and emergency measures. The use of unit-costs and lump-sums aims at reducing administrative burden, speeding up the payment process, and reducing the error rate. Secondly, DG SANTE has been involved in the development and roll-out of the corporate "EC Multi-annual Programming and Planning solution", developed by DGs DIGIT and BUDG. The tool is expected

<sup>18</sup> Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020

<sup>19</sup> DG SANTE returned payment credits of EUR 22.9 million under the EU4Health programme and EUR 15 million under the food safety domain to the EU 2022 budget during the global transfer.

to provide a ‘Financial Forecasting’ module to facilitate financial management and a ‘Multi-annual Programming & Planning’ tool for efficient management of programme planning and implementation.

### 3. Economy of controls

The main economy indicators monitored in 2022 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 2022 Unit Management Plans of October 2021 approved by the Director-General (for more detail on the indicators see Annex 7.2).

Payments made in the Food Safety policy area have decreased substantially in comparison to previous years further to the transfer of important parts of the budget to the executive agency HaDEA (see Table 2.1 and its explanations above). In 2022, HaDEA implemented about 65% of the payment credits, mainly to co-finance Member States’ veterinary and phytosanitary programmes. Close supervision and co-operation with HaDEA is established ensuring timely budget implementation. The remaining 35% implemented by DG SANTE concern the files relative to IT expenditure and the funding of Member States’ veterinary and plant emergency measures. The management of the latter is particularly demanding, the main cost-drivers being the diversity and complexity of the files in both technical and financial aspects. Efforts are ongoing to simplify financial management and thus reduce the cost of controls by broadening the use of lump-sums, ceilings or unit-costs.

**Table 2.4 Economy of controls – evolution over time**

Cost of controls as % of annual payments	Targets	2022		2021	
		Payments	Cost of controls	Payments	Cost of controls
		M€	%	M€	%
Grants to Member States in the Food Safety policy area	< 5%	<b>47,9</b>	<b>3,1%</b>	39,9	3,4%
Public procurement and other grants (including ESI in 2020-2021)	< 7%	<b>85,7</b>	<b>3,7%</b>	450,2	1,3%
Subsidy payments to agencies	< 1%	<b>333,6</b>	<b>0,4%</b>	362,8	0,3%
<b>Total</b>		<b>467,2</b>	<b>1,3%</b>	852,9	1,0%

Public procurement procedures are highly regulated, and 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”. The procurement procedures initiated in 2022 were oriented to the implementation of the MFF budget.

Cost drivers for the subsidy payments to agencies are mainly the intense 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, and the follow-up of the regular external evaluations of the agencies.

#### **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 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.

#### **2.1.2 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.

##### **1. European Court of Auditors**

###### **(a) 2021 DAS – compliance audit**

On 13 October 2022, the Court published its annual report (2021 DAS) on the implementation of the EU budget for the 2021 financial year. The structure of the Court's 2021 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. The Court's recommendation to improve the control of the implementation of the Advance Purchase Agreements for COVID-19 vaccines is addressed to HERA further to the transfer of these files from DG SANTE to HERA.

###### **(b) Court's special reports of 2022**

On 12 September 2022, the Court published the special report on EU COVID-19 vaccine procurement. The Court's report covered actions taken in the period July 2021- June 2022 and acknowledged that the centralised system for vaccine procurement succeeded in creating a broad and diversified portfolio of vaccine candidates and in procuring sufficient doses of COVID-19 vaccines. The Commission is now drawing on this experience and the lessons learned during the COVID-19 pandemic in its work to set up a strong European Health Union and improve the joint EU crisis preparedness and management. The Court's

recommendations have been accepted by the Commission. No recommendation was directly addressed to DG SANTE.

The Court published on 11 January 2023 the special report on tools facilitating travel within the EU during the COVID-19 pandemic. The Court concluded that, despite its limited competence in public health policy, the Commission moved fast to propose suitable technological solutions to facilitate travel. DG SANTE was associated to this audit and will follow up on the Court's recommendations related to the EU digital passenger locator forms and the EU Digital COVID Certificate.

### ***(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 food waste, animal welfare, food safety, cross-border health care, antimicrobial resistance (AMR), sustainable use of pesticides, and the protection of pollinators. Actions to address all open recommendations are well advanced with target dates for full implementation mostly in 2023 and 2024. Detail on the Court's recommendations and DG SANTE's follow-up actions are included in Annex 8.1.1.

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. Internal Audit Service of the Commission***

The IAS contributed to DG SANTE's Annual Activity Report for 2022 by submitting a "limited conclusion on the state of internal control" on 14 February 2023. Based on the audit work performed in the period 2018 to 2022, the IAS points to three open recommendations 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' recommendations". The three recommendations pertain 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. The very important recommendations and DG SANTE's actions are explained in Annex 8.1.2.

DG SANTE believes that the mitigating measures put in place do 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.

## ***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.

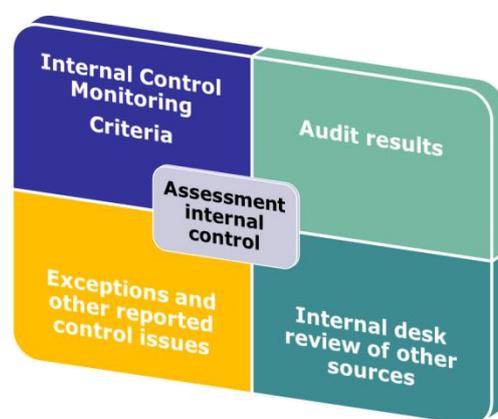
### 2.1.3 Assessment of the effectiveness of internal control systems

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.

Directorate-General 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. DG SANTE management assessed the effectiveness of its internal control system and its results following 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.



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. These relate to ethics, staff allocation and professional development, functions that are only partially under DG SANTE management. To strengthen its internal controls in these areas, DG SANTE organised an interactive workshop on ethics and professional integrity for DG SANTE staff in January 2022 and will continue to do so in close co-operation with OLAF, DG HR and IDOC. 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.

Further to the 2021 transfer of budget implementation tasks to HaDEA and of tasks related to the EU’s health emergency response and preparedness to HERA, DG SANTE reorganised its management structure. The new organisation chart entered into force on 1 October 2022. It is designed to reflect DG SANTE’s priorities more clearly, including its contribution to the Green Deal and the digital transitions and the DG’s leading work on the creation of the European Health Union developed as a result of the pandemic. As the reorganisation took place in the last quarter of 2022, it is too early to draw conclusions on how the reorganisation

improved, for example, DG SANTE's management of change or its staff allocation and achievement of policy objectives.

Due to the organisational changes and Directors having left DG SANTE, five acting Directors and one acting Deputy Director-General are currently ensuring business continuity. The recruitment procedures for the Directors have been launched in late 2022. As a consequence of the reorganisation, DG SANTE postponed its revision of the internal control strategy to 2023.

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 by the Director-General (more detail is given in Annex 7.1.1.2).

Throughout 2022, DG SANTE faced an exceptionally high workload with a series of access to documents requests related to its procurement and grant procedures. Special care was taken to safeguard confidential commercial information and prevent leaks. DG SANTE followed its well-established procedures, and no control issue came to the attention of management. In reply to the Ombudsman's recommendation on public access to documents concerning the quality of medical masks distributed during the COVID-19 pandemic in mid-2020, the Commission agreed to disclose significant additional information to the complainant. The Ombudsman therefore closed the inquiry in May 2022. No further cases of maladministration as regards DG SANTE's activity have been identified by Ombudsman in 2022.

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.

#### **2.1.4 Conclusions on the assurance**

This section reviews the assessment of the elements already reported above (in Sections 2.1.1, 2.1.2 and 2.1.3), 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 2022, DG SANTE's on-the-spot control function has resumed gradually its on-site visits after having performed mostly remote audits due to travel restrictions and health concerns during the COVID-19 pandemic. Remote audits, partially or in full, will continue based on DG SANTE's good experience with this type of audit for certain purposes.

In 2022, DG SANTE's results of ex-post controls lead to an estimated risk at closure of 0,7% and thus did not exceed the materiality threshold of 2%. 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.

## **2.1.5 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 ,***

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

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

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

***Brussels, date 31 March 2023***

***(signature)***

***Sandra GALLINA***

## 2.2 Modern and efficient administration – other aspects

### 2.2.1 Human resource management

During 2022 the management of the COVID-19 crisis and Brexit fall out continued to require a lot of attention and caused still important disruption. The HERA created in 2021 was built up from scratch with the recruitment of 80 new staff. At the same time the Russian aggression against Ukraine created new unforeseen challenges in the Health domain.

It became rapidly clear that DG SANTE's pre-Covid organisational structure and allocation of resources was not up to the challenge anymore and a revision should not be postponed any further.

Therefore, the DG engaged in a reorganisation process aiming at rebalancing the resources allocated to the different policies, Directorates and Units. Moreover, the health crisis made clear that a more holistic 'One Health' vision needed to be introduced into the organisation. 'One Health' is a paradigm shift that requires all staff to converge and act in synch with such vision leaving behind the rather entrenched "silo approach" that partially persists.

The whole process took a long time as sufficient time was invested to explain the rationale behind the need for rapid adaptation and what it would entail in practice for the individuals concerned.

The reorganisation took effect on 1st October and included in some areas transition periods allowing sufficient time for concerned staff to deal with the difficult issue of moving files and posts between the different DG SANTE geographical sites.

Despite the difficult crisis working environment of the past years the results on DG SANTE of the HR Staff survey carried out by the end of 2021 turned out to be very positive. An increase by 6% points (from 70% to 76%) of overall Staff engagement figures and important improvement of the appreciation of the performance of DG SANTE Management. Considering these good results and the fact that DG HR committed to develop a far-reaching new HR strategy taking into account the results of the survey, it was considered not very efficient to start developing a proper local DG SANTE follow up. Instead, DG SANTE will dedicate its efforts on implementing the corporate plan.

Gender parity in middle management was achieved and the effort to ensure sufficient instream of female administrators was sustained. It will be continued as DG SANTE's reserve list for Health and Food Safety specialists became available in September and resulted in 106 laureates of which more than 50% are female.

Lastly, DG SANTE started to implement the Commission's workplace of the future policy with its Directorate based in Luxembourg moving towards dynamic collaborative offices in the Drosbach building.

A table of indicators is included in Annex 10.

## 2.2.2 Digital transformation and information management

### a) Digital transformation

Working towards the 'Next Generation Digital Commission' and addressing technical debt, DG SANTE contributed to the corporate modernisation exercise to understand the business and technical capabilities for the whole SANTE IT portfolio. The results of which were used to help steer SANTE's own rationalisation strategy by tightening follow-up of migrations and upgrades, decommissioning old technologies and creating transition plans to streamline and modernise our solutions portfolio.

Considerable efforts were deployed in 2022 on auditing our cybersecurity position and taking action where necessary to improve the security of our systems and data.

In parallel, SANTE has started a journey to change the sourcing model used to source and deliver IT projects, reducing the reliance on traditional Time and Means contracts and moving towards a more delivery, results-based approach. 150 consultants were moved to the new DIGIT TM-II contract in 2022, whilst a third of the total IT budget is now dedicated to service/delivery based contracts. Such contracts aim at reducing the administrative burden placed on officials and allowing our technical staff to concentrate on delivery for our DG.

DG SANTE also launched an AI task force in 2022, aimed at identifying business use cases where innovative technologies using artificial intelligence and machine learning could reduce the burden on staff and bring about efficiencies and cost savings through automation, and assistance during various mundane day-to-day tasks.

At the same time in 2022, we also put in place services in the cloud, deliver, host and operate modern IT solutions. These services can ensure continuous operation of systems, adequate cybersecurity and more cost and time efficient evolution of our systems. This infrastructure will be used to migrate existing systems but also host the new SANTE IT systems.

Digital transformation is a multi-year process and SANTE will continue its endeavours to help identify synergies and bring value to our business.

More detail is provided in Annex 10.

### b) Information management

DG SANTE put in place its Data and Digital Steering Committee to act 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 four times in 2022 defining its mandate, reviewing digital solutions and exchanging information across the DG. It proposed a data strategy which is currently under DG wide consultation.

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

DG SANTE has updated its corporate data assets in the interim solution for data management, published relevant data on the open data portal and contributed to information on country knowledge. More details on the indicators are presented in the Annex 10.

### c) Data Protection

In the field of data protection, DG SANTE followed the five objectives specified in the Commission's Data Protection Action Plan<sup>20</sup>.

Again, in 2022, DG SANTE reviewed and updated existing records to ensure that they reflect the reality of the processing operation. This time, the exercise focused more on correct division of responsibilities throughout the DG, as it shifted on many occasions due the reorganisation, 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.

Awareness raising activities continued throughout the year with regular general trainings to newcomers and specifically designed trainings and presentations, for example relating to technical implementation of data protection rules. Combined attendance of events on data protection awareness raising in DG SANTE reached 60% of all staff over the last three years. It is well above the 50% interim milestone that was set up in DG SANTE's Strategic Plan for 2022.

A specific exercise was carried out with the purpose to ensure the proper implementation of data protection principles in relation to IMSOC and its four components.

In 2022, the Data Protection Impact Assessment (on the Early Warning and Response System) and connected third countries assessment (from the data protection perspective) has been finalised and its discussion with the Data Protection Officer of the Commission started.

The files with the most important data protection impact in the legislative area, were the proposal on the European Health Data Space and the proposal on the Substances of Human Origin for which opinions of the European Data Protection Supervisor/European Data Protection Board were issued.

## **2.2.3 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. 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.

The transition to blended working arrangements provided an opportunity to implement a seasonal shutdown of a section of the building in Grange, Ireland, to reduce energy use in wintertime. Many meetings and audits continued by video conferences. The air handling

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<sup>20</sup> C(2018)7432) and the review (C(2020)7625

system serving two large conference rooms was enhanced to conserve energy and reduce heat wastage. In addition, to lead by example and promote the merits of the Commission proposal for the Sustainable Use of Pesticides Regulation, the use of harmful pesticides and herbicides at Grange site has been discontinued. This should have a positive impact on local biodiversity.

## 2.2.4 Examples of economy and efficiency

In 2022, DG SANTE has identified and implemented two initiatives to improve efficiency and economy in its financial processes.

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

In view of the adoption of the Single Market Programme (SMP 2021-2027), a full revision of the financing system for EU support to Member States for the implementation of veterinary programmes and emergency measures was launched in 2020, in cooperation with the JRC. The project aimed at fostering the use of unit-costs and lump-sums (as opposed to actual incurred costs) aiming at reducing administrative burden, reducing the error rate and speeding up the payment process. The revision continued throughout 2022 in close co-operation with HaDEA, now tasked – inter alia – with the implementation of the animal disease eradication programmes. In March 2022, the Director-General of DG SANTE issued a decision authorising the use of lump sum contributions for the annual and multiannual veterinary programmes under the Single Market Programme. The lump sums will, for a large part, be based upon unit costs for which the methodology was developed by the JRC. They will allow a major simplification in the financial management of the grants by reducing the ex-post desk controls and audits and shifting the checks to ex-ante assessment of the costs.

### 2) Planning process and financial management

DG SANTE is involved in discussions and workshops for the development of a common corporate initiative aiming to improve financial programming, planning and forecasting. The “EC Multi-annual Programming and Planning solution”, developed by DGs DIGIT and BUDG, is expected to provide: - A ‘Financial Forecasting’ solution for the high-level forecasts needed for central financial management; - A ‘Multi-annual Programming & Planning’ for programme planning and implementation. Further to the first workshops and tests and the establishment of the Programme charter and Governance in 2021, additional workshops, studies and business cases were implemented in 2022, also to ensure the integration with the new accounting tool SUMMA, which is expected to replace the current tool (ABAC) in 2024.